

1 UNITED STATES DISTRICT COURT
2 DISTRICT OF NEVADA
3 BEFORE THE HONORABLE MIRANDA DU, DISTRICT JUDGE
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4 AMARIN PHARMA, INC., and :
5 AMARIN PHARMACEUTICALS :
6 IRELAND LIMITED, :
7 : No. 2:16-cv-02525-MMD-NJK
8 Plaintiffs, :
9 : January 21, 2020
10 -vs- :
11 : Reno, Nevada
12 HIKMA PHARMACEUTICALS USA :
13 INC., et al., : Volume 5
14 Defendants. :
15 _____ :
16 :

17 TRANSCRIPT OF BENCH TRIAL

18 APPEARANCES:

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(Appearances continue on next page.)

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08:37:38

1 RENO, NEVADA, TUESDAY, JANUARY 21, 2020, 8:31 A.M.

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08:31:22 3
08:31:22 4 THE COURT: Good morning. Please be seated.
08:31:43 5 All right. Defendants' counsel ready to
08:31:43 6 proceed?

08:31:43 7 MR. BARABAS: Yes, Your Honor.
08:31:43 8 Your Honor, as our next witness defendants call
08:31:43 9 Mr. Ivan Hofmann.

08:32:05 10 And, Your Honor, may we approach with binders?

08:32:05 11 THE COURT: Yes.

08:32:05 12 MR. BARABAS: Thank you.

08:32:05 13 IVAN T. HOFMANN,
08:32:05 14 called as a witness on behalf of the Defendants,
08:32:05 14 was sworn and testified as follows:

08:32:05 15 THE CLERK: Please be seated.

08:32:05 16 Please state your full name and spell both your
08:32:05 17 first and last name for the record.

08:32:08 18 THE WITNESS: My name is Ivan T. Hofmann,
08:32:22 19 I-v-a-n, then Hofmann is H-o-f-m-a-n-n.

08:32:22 20 MR. BARABAS: May I proceed, Your Honor?

08:32:22 21 THE COURT: Yes.

08:32:22 22 DIRECT EXAMINATION

08:32:22 23 BY MR. BARABAS:

08:32:39 24 Q Okay. Mr. Hofmann, where are you currently employed?

08:32:43 25 A I'm a vice-president and managing director at Gleason,

08:32:49 1 which is an economic finance and accounting consulting firm.

08:32:53 2 And I'm the leader of the intellectual property practice.

08:32:57 3 Q Would you please briefly summarize your education.

08:33:00 4 A Sure. I graduated magna cum laude from the University of
08:33:09 5 Notre Dame with majors in both economics and accounting.

08:33:11 6 Q What is the nature of your work in the area of
08:33:13 7 pharmaceutical products?

08:33:15 8 A So sometimes -- well, I'm regularly consulting in the
08:33:21 9 area of pharmaceutical economics and specifically issues
08:33:25 10 involving intellectual property.

08:33:27 11 Sometimes it's in a dispute setting like this where
08:33:30 12 I'm addressing issues like commercial success and nexus and
08:33:34 13 other secondary considerations of nonobviousness. Sometimes
08:33:39 14 it relates to things like damages, irreparable harm, et
08:33:44 15 cetera.

08:33:44 16 Then outside of the dispute setting, I regularly
08:33:47 17 assist companies in the life sciences industry, including
08:33:51 18 pharmaceutical companies, on things like valuation of
08:33:55 19 intellectual property, monetization of intellectual property,
08:33:59 20 licensing intellectual property, as well as product pipeline
08:34:04 21 consulting, pricing, promotion agreements, et cetera.

08:34:09 22 Q How many pharmaceutical and biologic products have you
08:34:12 23 analyzed?

08:34:13 24 A Oh, over the last few decades, it's been certainly more
08:34:17 25 than hundred covering virtually every major therapeutic class

08:34:22 1 of drugs.

08:34:22 2 Q Have you worked on products that are used to reduce
08:34:26 3 triglyceride levels in adult patients with severe
08:34:31 4 hypertriglyceridemia?

08:34:31 5 A I have, and I think we heard about some of those drugs
08:34:36 6 last week, both in and out of a dispute setting. I've studied
08:34:42 7 the markets and provided consulting services on the
08:34:49 8 fenofibrate products, Niaspan, and obviously the omega-3s.

08:34:54 9 Q Have you been engaged by the United States Patent and
08:34:58 10 Trademark Office to analyze issues involving intellectual
08:35:00 11 property?

08:35:00 12 A I have. On numerous occasions I've been hired by USPTO
08:35:07 13 and the Office of the Solicitor to analyze economic issues
08:35:12 14 involving intellectual property, and I've testified in Court
08:35:15 15 on behalf of the U.S. Government in regards to those issues
08:35:19 16 specifically involving commercial success and nexus.

08:35:23 17 MR. BARABAS: Mr. Gross, if we could put up
08:35:26 18 DX 2223.

08:35:26 19 BY MR. BARABAS:

08:35:27 20 Q Mr. Hofmann, would you please identify this document.

08:35:30 21 A Yes, this is my summary curriculum vitae or CV.

08:35:37 22 MR. BARABAS: And, Your Honor, if we could enter
08:35:40 23 DX 2223 into evidence.

08:35:43 24 THE COURT: Any objection?

08:35:44 25 MR. M. KENNEDY: No objection, Your Honor.

08:35:45 1 THE COURT: DX 2223 is admitted.

08:35:45 2 (Defendants' Exhibit 2223 received in
08:35:45 evidence.)

08:35:45 3 BY MR. BARABAS:

08:35:51 4 Q Mr. Hofmann, have you previously been designated as an
08:35:54 5 expert by a court?

08:35:55 6 A I have. I've been designated as an expert in federal and
08:35:59 7 state court, before the United States International Trade
08:36:03 8 Commission, before the Patent Trial and Appeal Board, and
08:36:06 9 before various domestic and international arbitration panels.

08:36:11 10 Specifically, I've been recognized as an expert in
08:36:15 11 pharmaceutical economics by many federal courts throughout the
08:36:15 12 country.

08:36:22 13 MR. BARABAS: Your Honor, defendants' offer
08:36:24 14 Mr. Hofmann as expert witness in pharmaceutical economics.

08:36:29 15 MR. M. KENNEDY: No objection, Your Honor.

08:36:30 16 THE COURT: The Court will certify Mr. Hofmann
08:36:34 17 as an expert in pharmaceutical economics.

08:36:34 18 BY MR. BARABAS:

08:36:35 19 Q Mr. Hofmann, what were you asked to do on this matter?

08:36:38 20 A I was asked to review and respond to the claims of
08:36:41 21 commercial success and nexus advanced by plaintiffs' witness,
08:36:47 22 Dr. Nicholson.

08:36:49 23 Q Have you prepared slides to assist the Court in your
08:36:53 24 testimony today?

08:36:53 25 A I have.

08:36:54 1 Q And you mentioned commercial success. What is your
08:36:58 2 understanding of what that means in the context of your
08:37:00 3 analysis?

08:37:01 4 A So I have a little summary slide here.

08:37:05 5 Essentially it's my understanding that commercial
08:37:08 6 success is a legal construct that's been established through
08:37:11 7 case law but is grounded in economics.

08:37:15 8 The main premise is that -- is this concept that if
08:37:20 9 a product is economically successful or experiences
08:37:25 10 marketplace success, that may provide objective evidence of
08:37:29 11 nonobviousness in an invalidity patent case under certain
08:37:34 12 circumstances.

08:37:35 13 And what one does is one analyzes various economic
08:37:41 14 metrics, both quantitatively and qualitatively, things like
08:37:47 15 profitability, market share, revenue, et cetera, and then
08:37:50 16 looks at whether that marketplace performance is attributable
08:37:54 17 to the claims of the patented invention, or whether there's
08:37:59 18 nexus between that marketplace performance and the claims of
08:38:03 19 the patents-in-suit.

08:38:05 20 Q All right. You mentioned nexus. So what is your
08:38:08 21 understanding of nexus?

08:38:10 22 A Yeah. So I think we've heard a couple of technical
08:38:14 23 experts last week talk about nexus in the context of other
08:38:19 24 secondary considerations of nonobviousness, and it's a
08:38:22 25 common -- you know, it's the same concept.

08:38:24 1 Basically, though, when we look at it from economic
08:38:28 2 perspective, we're looking at the marketplace performance of
08:38:32 3 the product and whether that marketplace performance is driven
08:38:36 4 by and attributable to the alleged novelty of the claimed
08:38:41 5 invention and not by other factors unrelated to the alleged
08:38:45 6 novelty of the claimed invention.

08:38:48 7 Said differently, the plaintiffs, in order to
08:38:51 8 establish commercial success, have to show that there's a
08:38:54 9 causal correlation between the marketplace performance of the
08:39:00 10 product and the claims of the patents-in-suit, the unique
08:39:05 11 merits of the patents-in-suit.

08:39:07 12 This is called nexus. And if they do not establish
08:39:11 13 that nexus or causal correlation between the marketplace
08:39:15 14 performance and the claims of the patents-in-suit, there's no
08:39:19 15 nexus and there's no ability to find commercial success as
08:39:22 16 potential objective indicia of nonobviousness.

08:39:27 17 Q Okay. If we could turn to the next slide, DDX 8.4, and
08:39:32 18 if we could take your opinions of commercial success and nexus
08:39:38 19 one at a time. What is your first opinion?

08:39:40 20 A So, the first and most central opinion, even before you
08:39:44 21 get to nexus, is that the marketplace performance of Vascepa
08:39:47 22 is not indicative of a product that's been a commercial
08:39:51 23 success or a marketplace success.

08:39:54 24 As I'll explain in more detail, Vascepa has not been
08:39:58 25 able to generate annual profits in any year and has been

08:40:02 1 massively unprofitable on a cumulative basis. So that's
08:40:07 2 looking at it in absolute terms.

08:40:09 3 And then on a relative basis, the market share of
08:40:13 4 Vascepa relative to other triglyceride-lowering drugs has been
08:40:18 5 very small, it's in a low single digit percentage.

08:40:21 6 Q What is your second opinion with respect to commercial
08:40:24 7 success and nexus?

08:40:25 8 A Well, I think, you know, like I said, I'm here to respond
08:40:29 9 to Dr. Nicholson, but I'm going on before him.

08:40:32 10 And so I think we're going to hear from
08:40:35 11 Dr. Nicholson that he believes that we can look at forecasts
08:40:39 12 of potential future performance and look at those as potential
08:40:44 13 economic evidence of commercial success.

08:40:47 14 But I reject both the methodology that he's used,
08:40:53 15 the Net Present Value calculation that I think he's going to
08:40:56 16 advance, and, in any event, everything that he's advancing in
08:41:02 17 terms of future performance is tied to things that lack nexus.
08:41:07 18 They relate to the REDUCE-IT trial and things unrelated, as I
08:41:11 19 understand it, to the claims of the patents-in-suit.

08:41:13 20 Q All right. If we could turn to the next slide DDX 8.5,
08:41:19 21 Mr. Hofmann, what is your third opinion with respect to
08:41:19 22 commercial success and Nexus?

08:41:27 23 A Sure. So the first two opinions is there's no evidence
08:41:27 24 of marketplace success. If Your Honor concludes that there is
08:41:31 25 no evidence of marketplace success, you don't even need get

1 into nexus because you don't have the economic criteria to
2 even get to commercial success.

3 But if one considers marketplace performance, one
4 has to look at nexus, and the marketplace performance of
5 Vascepa simply lacks nexus to the claims of the
6 patents-in-suit.

7 What I'll explain in a little more detail is I think
8 it's undisputed that the vast majority of all sales of Vascepa
9 don't fall under the method claims covered by the
10 patents-in-suit that are at issue from a validity perspective
11 that we're addressing here in court, and I have both
12 quantitative and qualitative evidence that explains that.

13 In addition to the fact that the vast majority of
14 the prescriptions are unrelated to the patents-in-suit,
15 there's also extrinsic factors that drive the sales of Vascepa
16 that also do not have a nexus to the claims of the
17 patents-in-suit and explain the marketplace performance, and
18 these are marketing and promotion as well as discounts,
19 rebates, and other incentives.

20 Q All right. You've mentioned the patents-in-suit. What
21 is your understanding of the patents-in-suit?

22 A Well, I think we heard from witnesses last week that
23 these are method patents that are directed to patients that
24 present with very high triglycerides, which I understand means
25 patients with greater than 500 milligrams per deciliter in

08:43:13 1 their system, and the method of treating that condition with
08:43:19 2 icosapent ethyl.

08:43:20 3 Q Okay. So you've testified earlier that profitability is
08:43:23 4 one the economics metrics important to the consideration of
08:43:28 5 potential commercial success. Would you please explain why.

08:43:31 6 A Sure. So this goes back to the framework of why I'm even
08:43:40 7 here and why we're potentially looking at the marketplace
08:43:44 8 performance of Vascepa.

08:43:46 9 What we're look at is what would have motivated
08:43:49 10 another company or a person of ordinary skill in the art to
08:43:52 11 conceive of the alleged invention as of the priority date, and
08:43:57 12 what courts look to is, in some situations, this, you know,
08:44:02 13 marketplace performance.

08:44:04 14 And marketplace performance, from an economic
08:44:10 15 perspective, it's very critical to look at profitability
08:44:14 16 because, from an economic perspective, what players, you know,
08:44:19 17 potential competitors, or persons of ordinary skill in the art
08:44:23 18 are looking to do is make profits to generate a return on
08:44:27 19 dollars invested, and that would be the type of -- one of the
08:44:29 20 types of economic motivation that could theoretically have
08:44:34 21 caused someone to conceive of the alleged infringement.

08:44:36 22 Q Did you review any profit and loss statements for
08:44:40 23 Vascepa?

08:44:40 24 A I did.

08:44:44 25 Q And what profit and loss statements did you analyze?

08:44:47 1 A So, I think I prepared a summary slide that Amarin
08:44:50 2 produced what are called product P and L, or product profit
08:44:56 3 and loss statements from 2008 through 2018, and in order to
08:45:01 4 make it easier to look at them, I summarized them on this
08:45:06 5 slide.

08:45:06 6 Q Let me stop you there. What did you find in your
08:45:09 7 analysis of Amarin's operating performance for Vascepa?

08:45:13 8 A So, I mean, basically what a product profit and loss
08:45:18 9 statement shows is the net sales less cost of goods sold less
08:45:23 10 some of the significant operating expenses like selling
08:45:26 11 general and administrative expenses and research and
08:45:29 12 development expenses.

08:45:31 13 And the bottom line in terms of the operating loss
08:45:35 14 I've highlighted in yellow, and what we see is that before
08:45:39 15 Vascepa launched, Amarin incurred pretty significant losses of
08:45:46 16 \$267,000,000. These related to the R&D which was used to
08:45:54 17 develop the product and then the administration and general
08:45:59 18 expenses that predate the launch of the product.

08:46:03 19 Then starting in 2013 through 2018, the period of
08:46:07 20 time for which data is -- was produced by Amarin and available
08:46:12 21 to me, we can see that they've generated tens of millions of
08:46:18 22 dollars a year in losses, if not hundreds of millions of
08:46:22 23 dollars a year in losses, for each and every year for the six
08:46:25 24 years that data was available and Amarin's been on the market.

08:46:29 25 And so the bottom line one gets to in the far right

08:46:34 1 bottom corner is that Amarin has generated \$863 million,
08:46:40 2 nearly a billion dollars, in total losses through 2018 related
08:46:45 3 to the sales of Vascepa.

08:46:47 4 Q And so bottom line, what have you concluded regarding the
08:46:50 5 lack of profitability of Vascepa?

08:46:53 6 A Well, this -- you know, from an economic perspective,
08:46:58 7 this is a very strong indication that this product has not
08:47:01 8 exhibited marketplace success. In fact, it indicates that it
08:47:06 9 has generated significant losses.

08:47:09 10 And what's important about these numbers is these
08:47:11 11 are actual numbers. This is the objective performance of the
08:47:16 12 product in the marketplace. These aren't forecast, these
08:47:21 13 aren't hopes and dreams, these are what has happened in the
08:47:24 14 marketplace over the course of a lengthy period that the
08:47:27 15 product has been on the market and generated massive losses.

08:47:30 16 Q Okay. Mr. Hofmann, on the bottom left of the slide is
08:47:34 17 PX 590, and what is that document?

08:47:36 18 A That was the underlying source documents that Amarin
08:47:41 19 product P and Is prepared in the normal course of business.

08:47:44 20 Q And that's a document that you relied upon in preparing
08:47:49 21 this demonstrative?

08:47:50 22 A It is.

08:47:51 23 MR. BARABAS: And, Your Honor, I'd like to move
08:47:52 24 that into evidence, but before I do, I spoke to Mr. Kennedy,
08:47:57 25 and plaintiffs I believe would just like the chance to review

1 this and other documents as they may contain third-party
2 confidential information before they're on the public record.

3 MR. M. KENNEDY: Well, Your Honor, just more
4 specifically, we don't believe the courtroom needs to be sealed
5 today for purposes of what is going to be discussed in court.

6 But some of the underlying exhibits are quite
7 voluminous, and just so, in an abundance of caution, we would
8 like the opportunity to review the underlying exhibits before
9 they hit the public docket, similar to what we did last week
10 with Dr. Ketchum.

11 THE COURT: And this is with respect to PX 590?

12 MR. M. KENNEDY: Yes, and there will be some
13 other exhibits coming up, and I'm happy to individually
14 identify them if necessary. But for purposes of what's going
15 to be in court today, I don't think we need to seal the
16 courtroom.

17 THE COURT: All right. So Exhibit 590 is
18 admitted subject to some potential redaction.

19 MR. M. KENNEDY: Thank you, Your Honor.

20 MR. BARABAS: Thank you, Your Honor.

21 And, then, Your Honor, defendants' would also
22 move to admit DDX 8.6 as a summary exhibit.

23 MR. M. KENNEDY: No objection, Your Honor.

24 THE COURT: Have you shown 3.6 yet?

25 MR. BARABAS: I'm sorry, I meant to say 8.6. If

08:49:04 1 said 3.6, it's the exhibit on the screen.

08:49:04 2 THE COURT: 8.6. I think I misunderstood.

08:49:07 3 MR. BARABAS: I'm sorry.

08:49:07 4 THE COURT: Yes, that request is granted.

5 THE DEFENDANT: Thank you, Your Honor.

6 (Plaintiffs' Exhibit 590 received in
evidence.)

7 (Defendants' Exhibit 8.6 received in
evidence.)

8 BY MR. BARABAS:

08:49:12 9 Q Mr. Hofmann, in your review of Amarin's financial
08:49:15 10 statements, would you please describe the sales performance of
08:49:18 11 Vascepa.

08:49:18 12 A Sure. And that's -- that's shown on the top line, the
08:49:23 13 net product sales line item.

08:49:25 14 I mean, what we can see is that, yes, Vascepa has
08:49:30 15 generated some level of growing sales, getting up to about 228
08:49:37 16 million in 2018, but those growing sales have come at a great
08:49:44 17 cost, and those are the selling and administrative expenses
08:49:47 18 that we see, as well as some of the R&D expenses.

08:49:51 19 So what we see is that while there has been some
08:49:54 20 level of growth in sales, they've generated massive losses
08:49:59 21 every year and on a cumulative basis for Vascepa.

08:50:04 22 Q So why did you discuss profitability rather than just
08:50:07 23 sales earlier?

08:50:08 24 A Well, I think that if one just looks at sales and one
08:50:14 25 just looks at sales on an absolute basis or sales growth, it's

an incomplete picture and I think is economically unsound.

You know, you have to look at the costs associated with generating those sales in order to get the true economic picture.

Again, we're trying to analyze whether there was an economic motivation for others to have conceived of the alleged invention by studying what's happened since the launch of the product, and what we see since the launch of the product is massive annual and cumulative losses.

Q Mr. Hofmann, you stated in your summary of opinions that the market share of Vascepa does not demonstrate marketplace success. Would you please explain what you mean by that.

A Sure. So what we're looking at on this slide was the absolute performance or kind of the performance of Vascepa in a vacuum.

As I understand it, it's important and it makes economic sense to also look at the relative performance of Vascepa in the marketplace compared to other TG-lowering products to see how it's performed on a relative basis, which, again, is a measure or metric to consider on whether the product has been a marketplace success.

Q How would you define the relevant market in which to look at?

A Well, I think we've heard about a lot of the products in court last week. I think Dr. Nicholson and I use the same

08:51:53 1 market which includes prescription, triglyceride-lowering
08:51:58 2 drugs, which are like the fenofibrates and Niaspan and
08:52:05 3 gemfibrozil and other omega-3s, I guess, Lovaza.

08:52:10 4 MR. BARABAS: If we could turn to DDX 8.7.

08:52:10 5 BY MR. BARABAS:

08:52:13 6 Q Mr. Hofmann, how did you evaluate Vascepa's market share
08:52:17 7 in the triglyceride reducing market with reference to the
08:52:21 8 demonstrative?

08:52:22 9 A Yes. So I actually prepared a few graphs to cut the data
08:52:26 10 a few different ways, and when I say the data, what I'm
08:52:31 11 referring to is IQVIA data.

08:52:35 12 IQVIA is a data aggregator, a service provider, it
08:52:41 13 used to be known as IMS Health, and it's a widely-recognized
08:52:47 14 data aggregator with respect to pharmaceutical information.

08:52:52 15 It's regularly used by pharmaceutical companies, and
08:52:57 16 regularly used by people like myself in a dispute setting and
08:53:03 17 in a consulting setting to look at the market dynamics.

08:53:09 18 So taking that data, I prepared this stacking graph
08:53:14 19 that we see on screen.

08:53:16 20 Q And looking at the stacking graph, what did you determine
08:53:19 21 from your analysis?

08:53:21 22 A Sure. So what this stacking graph does is it takes total
08:53:28 23 prescriptions, and IQVIA uses the abbreviation TRX for
08:53:34 24 prescriptions.

08:53:35 25 And what a stacking graph does, if you look at the

vertical access on the far left side, is, as of 2013, there were a total of about \$32 million -- not dollars, sorry -- prescriptions that were prescribed according to IQVIA for triglyceride-lowering products. So that's the total market.

And then what the different layers within the stacking graph represent are the portion of those total prescriptions related to each of the different product category classes.

So the largest blue one is the fenofibrate products, and then you have Niacin, Lovaza, gemfibrozil, and that tiny red sliver there at the top is Vascepa's share of the market.

And then what I did is we can see that the market has been declining since 2013, and we can see that Vascepa has only been able to garner on a cumulative basis about 4.5 million prescriptions compared to the other triglyceride-lowering products which have totaled more than \$161 million -- or, I'm sorry, prescriptions.

So it really dwarfs the prescriptions that Vascepa has been able to attain which isn't indicative of a product that's been a marketplace success.

Q Okay. So looking at the bottom left of the slide, there's a reference to PX 391 which I believe is entitled Prescription View. Is that a document you relied upon in preparing this stacking graph?

A It is, it's the underlying IQVIA data on prescriptions.

08:55:22 1 MR. BARABAS: And, Your Honor, subject to any
08:55:24 2 redactions by plaintiffs, defendants would seek to enter
08:55:29 3 PX 391 into evidence.

08:55:31 4 MR. M. KENNEDY: No objection, with the
08:55:32 5 opportunity for reductions.

08:55:33 6 THE COURT: Thank you. 391 admitted.

08:55:36 7 MR. BARABAS: And defendants also seek to admit
08:55:37 8 DDX 8.7 as a summary exhibit.

08:55:40 9 MR. M. KENNEDY: No objection, Your Honor.

08:55:42 10 THE COURT: 8.7 is admitted as a demonstrative.

11 (Plaintiffs' Exhibit 391 received in
evidence.)

12 (Defendants' Exhibit 8.7 received in
evidence.)

13 BY MR. BARABAS:

08:55:47 14 Q Okay. If we could turn to the next demonstrative,
08:55:52 15 DDX 8.8, and this demonstrative is entitled Prescription Share
08:55:56 16 Analysis 2013 through November 2018.

08:55:59 17 Mr. Hofmann, with reference to this demonstrative,
08:56:02 18 what can you conclude?

08:56:04 19 A Yes. So this is the same dataset that we saw in the
08:56:07 20 stacking graph I just explained, but it's a different way to
08:56:10 21 cut the data and look at the data.

08:56:12 22 This takes that same period, from 2013 to 2018, the
08:56:21 23 period of time that Vascepa has been on the market, and looks
08:56:24 24 at, expressed as a percentage, how much the prescription share
08:56:29 25 has been for Vascepa relative to other triglyceride-lowering

08:56:33 1 drugs.

08:56:33 2 And what we can see with the red circle there is
08:56:37 3 they've only been able to garner a small single digit
08:56:40 4 percentage of about 3 percent in the marketplace.

08:56:45 5 And this is the entire amount of prescriptions.
08:56:49 6 This doesn't even get into the fact that most of these
08:56:53 7 prescriptions are written for patients that aren't covered by
08:56:57 8 the patents-in-suit.

08:56:59 9 So this shows that compared to the fenofibrates and
08:57:04 10 gemfibrozil and even other omega-3s, Vascepa has not been able
08:57:08 11 to garner significant market share, and, from economic
08:57:12 12 perspective, is not supportive of Vascepa being a marketplace
08:57:17 13 success.

08:57:18 14 MR. BARABAS: And defendants would move to admit
08:57:20 15 DDX 8.8 as a summary exhibit.

08:57:23 16 MR. M. KENNEDY: No objection, Your Honor.

08:57:24 17 THE COURT: DDX 8.8 is admitted as a
08:57:27 18 demonstrative.

08:57:27 19 (Defendants' Exhibit 8.8 received in
08:57:27 20 evidence.)

08:57:27 20 BY MR. BARABAS:

08:57:31 21 Q Okay. Mr. Hofmann, if we can turn to your next opinion.

08:57:33 22 You indicated that forecasted potential future
08:57:37 23 performance does not provide objective economic evidence of
08:57:42 24 commercial success. Please explain what you mean by that.

08:57:45 25 A Well, like said, I think we might hear from Dr. Nicholson

08:57:48 1 that -- I don't think he disagrees that the product has lost a
08:57:53 2 significant amount of money so far and has failed to generate
08:57:57 3 profits, but attempts to look at potential forecasts as what
08:58:04 4 he claims are potential evidence of objective economic
08:58:09 5 performance, and I just fundamentally reject that.

08:58:13 6 I think that looking at future hopes and aspirations
08:58:18 7 of what may or may not unfold in a very complex and dynamic
08:58:24 8 pharmaceutical marketplace does not represent objective
08:58:30 9 evidence of the product's performance in the marketplace, and,
08:58:34 10 if one does so, you know, one has really speculated on the
08:58:38 11 future performance which doesn't provide reliable evidence or
08:58:42 12 objective evidence of marketplace performance.

08:58:46 13 Q Is it meaningful that a company has hopes and aspirations
08:58:51 14 for future sales?

08:58:52 15 A Oh, I think it's very common that both companies and
08:58:56 16 analysts will undertake, you know, some amount of forecasting,
08:59:00 17 and I think, you know, they do so in good faith and do so with
08:59:05 18 the hopes that the forecasts will materialize.

08:59:10 19 But, of course, there is a long history of examples
08:59:16 20 of companies that -- and analysts that have made forecasts
08:59:20 21 that simply don't materialize.

08:59:22 22 And so it's really not, I think, objective evidence
08:59:26 23 on which one should rely in an economically sound way in order
08:59:31 24 to potentially establish objective evidence of nonobviousness
08:59:39 25 in the form of commercial success.

08:59:39 1 Q What is the relationship between actual financial results
08:59:43 2 and forecasts?

08:59:44 3 A Yeah. So, I mean, one thing that we can do objectively
08:59:49 4 is we can look at forecasts that maybe were made several years
08:59:56 5 ago and then compare those to the actual forecasts.

08:59:59 6 And I think what we find is, you know, oftentimes
09:00:03 7 the actual results can vary greatly from the forecasts that
09:00:09 8 were made, and that's a way to kind of test the reasonableness
09:00:13 9 or reliability of the forecasts.

09:00:15 10 Of course, forecasting way out into the future, we
09:00:19 11 just don't know. We're speculating on whether or not those
09:00:24 12 forecasts are going to materialize.

09:00:25 13 Q So who prepares forecasts?

09:00:28 14 A Well, I think commonly companies do internally for
09:00:33 15 budgeting purposes, for planning purposes, for project
09:00:36 16 approval purposes, and then we know that analysts that follow
09:00:40 17 companies and investing companies will commonly prepare
09:00:43 18 forecasts.

09:00:44 19 Q Is it generally true that different analysts will have
09:00:47 20 the same forecast for a product or company?

09:00:49 21 A No. I think what we see generally is that analysts make
09:00:55 22 different assumptions. They make different predictions about
09:01:00 23 what's going to happen.

09:01:01 24 And, in the pharma space, whether or not products
09:01:04 25 are going to be approved, whether or not different indications

are going to become on label, there's a long, you know, regulatory pathway, and there's also lot of uncertainty in the dynamics of a competitive prescription pharmaceutical product.

So what we see is that -- particularly in the pharmaceutical industry, a lot of disparity among analysts on future forecasts. There's also differences in how far out analysts will forecast, and so you can have temporal issues as well.

Q All right. Mr. Hofmann, your next opinion is that Dr. Nicholson's Net Present Value calculation is flawed and unreliable. Please explain your basis for this opinion.

A Well, I think what we see and what Dr. Nicholson advanced in a Net Present Value calculation is he's taken a number of analyst's reports, some of which only go out to 2020, two of which go out to 20 -- one goes out to 2027, and one goes out to 2029.

He's made some assumptions to project the ones out that only go out for a short period, and he's assumed that these forecasts and assumptions that he's made will come to fruition.

He's taken an average of those and then applied a discount rate, and then, you know, determined a Net Present Value.

All of that is based on a series of speculative assumptions, and assumptions that it's appropriate to average

09:02:45 1 these analyst's reports, and that somehow it's appropriate to
09:02:49 2 assume that these future projections for the next ten years
09:02:54 3 will materialize, and I just find that speculative and
09:02:58 4 unreliable.

09:02:59 5 Q Is a Net Present Value analysis a reliable economic
09:03:07 6 measurement for commercial success?

09:03:07 7 A Oh, in certain settings Net Present Value is a commonly
09:03:11 8 used tool, and I think in certain settings, you know, like
09:03:15 9 with project approval or, you know, different analysts may
09:03:21 10 look at net present value.

09:03:23 11 But, again, what we're here today to talk about, I
09:03:27 12 think, is objective evidence of marketplace performance and
09:03:31 13 whether that has a nexus to the claims of the patents-in-suit.

09:03:35 14 And I just don't think that net present value, when
09:03:38 15 you're speculating out for the next decade on what's going to
09:03:43 16 happen in the marketplace, is a reliable, objective measure of
09:03:48 17 marketplace performance, especially when we have, you know,
09:03:52 18 six years of actual marketplace activity that shows massive
09:03:58 19 hemorrhaging losses for Vascepa.

09:04:00 20 Q From your analysis, did Dr. Nicholson assess a
09:04:03 21 reasonableness of the forecasts on which he relies for his net
09:04:08 22 present value calculation?

09:04:09 23 A Well, that's another problem I have with the NPV analysis
09:04:15 24 that he advances is he takes these analysts' forecasts but
09:04:19 25 doesn't do anything to test the accuracy of them, and what

09:04:24 1 we -- what we can see is that some of the forecasts have been
09:04:28 2 very inaccurate.

09:04:29 3 Q Did Dr. Nicholson analyze the historical accuracy of the
09:04:35 4 industry analysts' projections?

09:04:37 5 A No, he didn't, and I think a good example of that is
09:04:42 6 H. C. WainWright.

09:04:43 7 Q Okay. And if we could turn to your own analysis. Did
09:04:48 8 you analyze the historical accuracy of the industry analysts'
09:04:52 9 projections referenced in Dr. Nicholson net present value
09:04:57 10 calculation?

09:04:57 11 A I did.

09:04:58 12 Q And what did you conclude?

09:04:59 13 A That they've been historically inaccurate for the periods
09:05:03 14 of time that we do have the ability to test the actual results
09:05:10 15 compared to the forecasts, and that really calls into question
09:05:14 16 the future forecasts and their reliability.

09:05:18 17 Q And I think you had mentioned H. C. WainWright. If we
09:05:21 18 could put up DDX 8.9. With reference to this demonstrative,
09:05:26 19 what conclusion did you draw from your analysis of H.C.
09:05:30 20 WainWright & Company's projections?

09:05:32 21 A Sure. So just to orient us to this slide, what I did was
09:05:38 22 I analyzed the forecasts or the predictions of two key
09:05:42 23 metrics, net revenue and operating income or loss.

09:05:47 24 And what I have in the top table is H.C. WainWright
09:05:52 25 published predictions or forecasts of net revenue for 2018.

09:05:59 1 So these are the predictions of what the revenues were going
09:06:02 2 to be in 2018 in a report published in 2015, a report
09:06:07 3 published in 2016, and a report published in 2017.

09:06:12 4 So these are all reports after commercialization and
09:06:15 5 approval of Vascepa, and they consistently predicted revenues
09:06:22 6 to be on the order of \$385 million.

09:06:25 7 And then what we see for 2018 is, in fact, actual
09:06:30 8 results were only 228 million for a variance of roughly
09:06:36 9 \$157 million. That's a huge dollar difference, as well as a
09:06:42 10 huge percentage difference, in what they had forecast revenues
09:06:46 11 to be versus what revenues actually were.

09:06:49 12 And then, importantly, I also looked at operating
09:06:54 13 income and loss from those same analysts' reports.

09:06:58 14 Now, H.C. Wainwright did reduce their predicted
09:07:02 15 operating income. In all periods they predicted positive
09:07:07 16 operating income of at least 77 million, and then that was in
09:07:13 17 2017, but then for 2016, they predicted 85 million, in 2015,
09:07:18 18 they predicted 128 million all related to what they thought
09:07:23 19 operating income would be in 2018.

09:07:25 20 We now have actual results for 2018, and not only
09:07:30 21 were they wrong, but they were wrong in that Amarin didn't
09:07:36 22 even generate income, they generated more than hundred million
09:07:39 23 dollars in losses. So they had \$108 million in losses.

09:07:44 24 And so those variances on the right represent the
09:07:47 25 delta or the difference between the operating income that

09:07:52 1 Wainwright initially projected compared to the huge losses
09:07:57 2 that Amarin actually experienced, and we're talking about
09:08:00 3 hundreds of millions of dollars.

09:08:03 4 Q Okay. Turning again to Dr. Nicholson's NPV calculation,
09:08:09 5 would Dr. Nicholson's Net Present Value calculation change if
09:08:12 6 an analyst's forecast was added or removed from his
09:08:15 7 calculation?

09:08:16 8 A Yes, it definitely would.

09:08:23 9 I did want to mention, too, that I got these
09:08:26 10 documents -- or these numbers from various analysts' reports
09:08:31 11 that are listed on the bottom left of the slide at 8.9. I
09:08:36 12 don't know that we covered that, but --

09:08:37 13 Q Yeah. And thank you for that.

09:08:39 14 On bottom left of the slide there are four documents
09:08:44 15 mentioned, there's DX 2061, DX 2065, DX 2066 and DX 2054, and
09:08:52 16 are these the underlying financial data you used to prepare
09:08:57 17 this demonstrative?

09:08:58 18 A They are.

09:08:59 19 MR. BARABAS: Your Honor, with the same caveats
09:09:01 20 about chance for redactions, defendants would seek to move
09:09:05 21 these exhibits into evidence.

09:09:06 22 And I should also mention for the record the pin
09:09:09 23 cite of DX 2061 is page 4, the pin cite of 2065 is page 4, the
09:09:17 24 pin cite of page -- of document 2066 is page 2, and the pin
09:09:21 25 cite of DX 2054 is page 72.

09:09:25 1 MR. M. KENNEDY: No objection, Your Honor.

09:09:26 2 THE COURT: All right. DX 2061, 2065, 2066, and
09:09:32 3 2054 are admitted.

09:09:32 4 (Defendants' Exhibits 2061, 2065, 2066
09:09:35 and 2054 received in evidence.)

09:09:35 5 MR. BARABAS: Okay. And defendants also seek to
09:09:38 6 admit DDX 8.9 as a demonstrative exhibit.

09:09:43 7 MR. M. KENNEDY: No objection, Your Honor.

09:09:43 8 THE COURT: 8.9 is admitted as demonstrative.

09:09:43 9 (Defendants' Exhibit 8.9 received in
09:09:49 evidence.)

09:09:49 10 MR. BARABAS: Thank you, Your Honor.

09:09:49 11 BY MR. BARABAS:

09:09:50 12 Q Turning back to Dr. Nicholson's Net Present Value
09:09:53 13 calculation, I'm going to ask you, Mr. Hofmann, would that
09:09:57 14 calculation change if an analyst's forecast was added or
09:09:59 15 removed from his calculations?

09:10:03 16 A Yes. One of the things that happened was Dr. Nicholson
09:10:06 17 issued a report, I responded and pointed out what an outlier
09:10:11 18 the H.C. Wainwright analyst's report was, and so he revised
09:10:17 19 his NPV calculation in his reply report.

09:10:20 20 And what we can see is simply removing one analyst's
09:10:24 21 report has massive -- has a massive impact and shows the
09:10:28 22 volatility and unreliability of the use of these analysts'
09:10:33 23 reports in his NPV calculation.

09:10:35 24 Q So if we could turn to DDX 8.10. And, Mr. Hofmann, with
09:10:40 25 reference to this demonstrative, would you please explain the

09:10:43 1 results of the two Net Present Value models.

09:10:46 2 A Sure. And this is kind of a busy graph so I'll try and
09:10:52 3 orient everyone.

09:10:55 4 So what we have starting on the left -- and the
09:10:58 5 horizontal axis is just a timeline, and then on the vertical
09:11:02 6 axis we have the values associated with Vascepa according to
09:11:11 7 the Net Present Value calculations undertaken by
09:11:15 8 Dr. Nicholson.

09:11:15 9 Now, there's a line at 2019, and to the left of that
09:11:20 10 line is the historical actuals which we know are actual
09:11:28 11 deepening losses for Vascepa since launch.

09:11:32 12 So starting in 2008, the orange line that you see
09:11:36 13 going down and down and down to 2019 is where we are as of
09:11:41 14 today, massive losses.

09:11:43 15 Then what Dr. Nicholson did in his opening report is
09:11:46 16 he forecasts future growth in Vascepa based on both the
09:11:54 17 analysts' reports as well as some assumptions that he's made
09:11:58 18 and a discount rate that he's applied.

09:12:01 19 And in his initial report he concluded, as the blue
09:12:06 20 line indicates, a steep growth in future Vascepa sales
09:12:10 21 resulting in a Net Present Value of \$1.9 billion.

09:12:15 22 Now, after I issued my report, it said, look, this
09:12:19 23 includes an H.C. Wainwright analyst's report that is a clear
09:12:24 24 outlier and doesn't make economic sense. He removed that in
09:12:30 25 his reply report and recalculated his Net Present Value, and

that's the orange line labeled as scenario 2.

And what you can see is just by removing H.C. Wainwright, one analyst, his NPV calculation dropped by \$1.52 billion, or 80 percent the value he claimed was there on his first report based on these forecasts going out about ten years, evaporates.

I think it's also important to note that even under Dr. Nicholson's theories, this product -- we're again trying to evaluate the economic motivation of a person of ordinary skill in the art or a competitor as of the priority date. So we're looking way back to the far left of this graph.

Even according to Dr. Nicholson, it isn't until maybe 2023 or 2027 that this product would break even. It's simply not indicative, even if this comes to pass, which, you know, I think we just don't know, it's a highly speculative theory to advance that there is economic motivations for others in the field to have conceived of the alleged invention based on this economic picture.

Q Okay. And then, Mr. Hofmann, looking at the bottom left of the summary exhibit, you see PX 1091 and PX 1102. Are those the Nicholson exhibits that you used to prepare your summary exhibit?

A They are.

MR. BARABAS: And, Your Honor, defendants seek to move -- or seek to move DDX 8.10 into evidence as a summary

09:14:20 1 exhibit.

09:14:22 2 MR. M. KENNEDY: No objection, Your Honor.

09:14:24 3 THE COURT: 8.10 is admitted as summary exhibit.

09:14:24 4 (Defendants' Exhibit 8.10 received in
09:14:24 evidence.)

09:14:28 5 BY MR. BARABAS:

09:14:28 6 Q Then, Mr. Hofmann, if we could turn to the next slide,
09:14:32 7 DDX 8.11. Did you identify any other examples which confirm
09:14:36 8 your conclusion regarding the subjective nature of the using
09:14:41 9 analysts' forecasts?

09:14:42 10 A Yes. So this is an exhibit from the Nicholson reply
09:14:46 11 report, and I thought it just highlights the hazard, from an
09:14:51 12 economic perspective, in relying on the analysts' reports that
09:14:57 13 Dr. Nicholson does in arriving at Net Present Value.

09:15:01 14 So he's identified here his estimated cumulative
09:15:05 15 income from 2008 to 2029 associated with five different
09:15:11 16 analysts.

09:15:12 17 Now, these numbers are not entirely put fourth by
09:15:15 18 those analysts. Like I said, a number of these analysts only
09:15:20 19 predicted out to 2020, and Dr. Nicholson made his own
09:15:24 20 assumptions about future performance based on those analysts'
09:15:29 21 reports.

09:15:29 22 But what we can see is that, you know, in one
09:15:33 23 extreme you have Jefferies who is predicting cumulative losses
09:15:38 24 of \$589,000,000, and, at the other extreme, H.C. WainWright
09:15:45 25 predicting \$7.9 billion in future income. That's a swing of

09:15:52 1 \$8.5 billion. I mean, that's just -- that shows the disparity
09:15:57 2 and unreliability of looking at these forecasts.

09:16:00 3 And then you have a few other analysts, Cantor
09:16:05 4 Fitzgerald and Citi and SunTrust. Cantor, you know, hows 746
09:16:10 5 million, Citi shows 523 million, and SunTrust shows nine
09:16:14 6 ninety-two.

09:16:15 7 Now, the Citi and the SunTrust are all -- or the
09:16:17 8 vast majority -- Nicholson assumptions, not their actual
09:16:22 9 predictions.

09:16:22 10 But, in any event, you have variances among these
09:16:25 11 analysts of hundreds and hundreds of millions of dollars, and
09:16:30 12 from economic perspective, this just doesn't provide objective
09:16:34 13 evidence of actual marketplace performance and what is
09:16:39 14 reasonably relied upon in assessing the economic performance
09:16:43 15 of a product in the marketplace.

09:16:45 16 Q So how does this chart impact your critique of
09:16:49 17 Dr. Nicholson's Net Present Value calculations?

09:16:51 18 A Well, it's the combination of this, as well as the last
09:16:54 19 graph, as well as the H.C. Wainwright example.

09:16:58 20 Simply, from a methodological perspective, I think
09:17:04 21 it's unsound to look at speculative long-term assumptions with
09:17:10 22 respect to future marketplace performance as purported
09:17:14 23 objective evidence of marketplace performance. It just
09:17:19 24 doesn't provide evidence of marketplace success for the
09:17:22 25 purposes of commercial success.

09:17:23 1 Q Okay. So, Mr. Hofmann, you've heard a lot about
09:17:27 2 REDUCE-IT since you've been at this trial, and with that in
09:17:30 3 mind, do you have any other disagreements with Dr. Nicholson's
09:17:33 4 use of the Net Present Value of Vascepa as evidence of
09:17:36 5 commercial success?

09:17:37 6 A Well, that's another huge, huge issue with the
09:17:41 7 methodology and the theory advanced with respect to the NPV
09:17:48 8 calculation.

09:17:48 9 I think we've heard a lot of testimony last week
09:17:53 10 about the REDUCE-IT trial and the additional indication being
09:17:56 11 added to the label for Vascepa.

09:17:59 12 And I think even if, somehow, these future sales and
09:18:04 13 future projections do come to pass, it's pretty clearly
09:18:09 14 evident that any of the future upside is really tied to the
09:18:13 15 REDUCE-IT trial and to patients who present with less than
09:18:18 16 500 milligrams per deciliter and not covered by the claims of
09:18:24 17 the patents-in-suit.

09:18:25 18 So even if that future growth and upside does come
09:18:29 19 to pass, it lacks a nexus to the claims of the
09:18:33 20 patents-at-suit.

09:18:33 21 Q All right. You mentioned nexus. Would you please remind
09:18:36 22 us of your understanding of nexus.

09:18:39 23 A Yeah, so I think at the outset I explained that one has
09:18:43 24 to look at marketplace performance, but then one also has to
09:18:47 25 make sure that the marketplace performance is tied to the

1 alleged novelty of the claims of the patents-in-suit in order
2 to establish nexus to potentially look at commercial success.

3 And if one doesn't have a nexus, if the sales or
4 marketplace performance, whether you're looking at historical
5 or future, are tied to things that aren't covered by the
6 patents-in-suit, then there's no nexus and no commercial
7 success.

8 Q Please explain what you mean when you testified earlier
9 that the performance of Vascepa lacks nexus to the asserted
10 claims of the patents-in-suit.

11 A Well, I think what I was explaining is that based on the
12 historical data, both qualitatively and quantitatively, as
13 well as some forward-looking statements by analysts, it's very
14 clear that the vast majority of historic prescriptions relate
15 to patients that aren't covered by the claims of the
16 patents-in-suit, and that's only going to be exacerbated into
17 the future in that future prescriptions, now that REDUCE-IT
18 has come to pass and has been added to the label, I think
19 we're going to see an even greater proportion of prescriptions
20 being not covered by the patents-in-suit and lacking nexus.

21 Q And then are there any other factors that are unrelated
22 to the assert claims in the patents-in-suit that you would
23 like to discuss or address?

24 A Yeah. So in addition to the lack of nexus associated
25 with the prescribing behavior or prescriptions, there are

09:20:28 1 those extrinsic factors I touched on at the outset, marketing
09:20:32 2 and promotion, as well as discounts, rebates and other
09:20:36 3 incentives.

09:20:37 4 Q All right. So we can take either each of those one at a
09:20:40 5 time. But first, again, what is your understanding of the
09:20:43 6 patents-in-suit?

09:20:43 7 A That it relates to a method of using icosapent ethyl for
09:20:46 8 patients who present with very high triglycerides being
09:20:50 9 defined as greater than 500 milligrams per deciliter.

09:20:54 10 Q Did you perform an analysis to estimate the number of
09:20:57 11 sales in prescriptions that potentially may not be covered by
09:21:01 12 the asserted claims of the patents-in-suit?

09:21:04 13 A I did.

09:21:04 14 Q And what did that analysis show? Actually, let me
09:21:08 15 rephrase that. What was that analysis based on?

09:21:12 16 A Yeah, so I had mentioned this data aggregator, IQVIA,
09:21:16 17 which is again commonly used in the pharmaceutical industry.

09:21:21 18 They prepare a dataset referred to as NDTI data, and
09:21:28 19 what that dataset does is it breaks out the diagnosis or the
09:21:33 20 reasons for which a patient is prescribed a particular
09:21:37 21 product.

09:21:40 22 And so I analyzed that data in order to figure out
09:21:43 23 the frequency of prescriptions related to patients that
09:21:48 24 present with very high triglycerides versus patients that fall
09:21:53 25 into other categories.

09:21:55 1 MR. BARABAS: Okay. If we could turn,
09:21:57 2 Mr. Gross, to slide DDX 8.12.

09:21:57 3 BY MR. BARABAS:

09:22:01 4 Q And, Mr. Hofmann, this slide is entitled Triglyceride
09:22:07 5 Levels. Would you please explain what is included in the data
09:22:10 6 here related to use of Vascepa.

09:22:13 7 A Sure. And we've seen slides similar to this last week.
09:22:16 8 You know, essentially this provides the categories that the
09:22:20 9 NDTI data tracks, the patient prescription usage.

09:22:25 10 The top category, the greater than 500 milligrams
09:22:30 11 per deciliter, that's my understanding of what the severe or
09:22:33 12 very high triglyceride levels are that may be covered by the
09:22:40 13 claims in the patents-in-suit.

09:22:42 14 The other categories would not be covered by the
09:22:40 15 claims of the patents-in-suit.

09:22:44 16 Q Okay. Then DX 2039 at page 3, is that the underlying
09:22:53 17 data that you used to prepare this summary exhibit?

09:22:56 18 A It is.

09:22:57 19 MR. BARABAS: And defendants seek to move
09:23:01 20 DDX 8.12 into evidence as a summary exhibit.

09:23:05 21 MR. M. KENNEDY: No objection, Your Honor.

09:23:06 22 THE COURT: 8.12 is admitted as a summary
09:23:10 23 exhibit.

09:23:10 24 (Defendants' Exhibit 8.12 received in
09:23:10 evidence.)

09:23:11 25 MR. BARABAS: And, Mr. Gross, if now if we could

09:23:14 1 turn to DDX 8.13.

09:23:14 2 BY MR. BARABAS:

09:23:16 3 Q Mr. Hofmann, with reference to this exhibit, would you
09:23:21 4 please describe your analysis of the NDTI data.

09:23:27 5 A Sure. So NDTI, again using those categories we just
09:23:31 6 looked at, tracks what they call drug appearances, which is,
09:23:36 7 you know, based on survey data how prescribers identify what
09:23:43 8 their patients are presenting with in terms of why they're
09:23:46 9 prescribing Vascepa.

09:23:47 10 And so what I did on the left graph is by year I
09:23:54 11 tracked in blue the number of -- or the percentage of
09:24:00 12 prescriptions that were written for patients that presented
09:24:03 13 with the very high triglyceride levels of greater than
09:24:09 14 500 milligrams per deciliter.

09:24:11 15 And then by year in red I tracked those that were
09:24:15 16 off-label that were less than 500 milligrams per deciliter.

09:24:20 17 And what you can see when you look at it on an
09:24:23 18 annual basis is that each and every year the vast majority of
09:24:27 19 drug appearances or patients that are prescribed Vascepa are
09:24:32 20 receiving it for triglyceride levels lower than 500, and only
09:24:40 21 the minority would fit into the greater than 500 on-label
09:24:46 22 category.

09:24:49 23 Then what I did is I took that same data from the
09:24:53 24 bar chart and put it into a pie chart in the right. The pie
09:24:57 25 chart basically takes that entire period so not on an annual

09:25:00 1 basis but looking at 2013 to 2018 and what we see is that
09:25:05 2 about three-quarters of the prescriptions are off-label or
09:25:11 3 would not be covered by the claims of the patents-in-suit, and
09:25:15 4 only about a quarter of the prescriptions during the period
09:25:19 5 that Vascepa has been on the market would fall under the
09:25:24 6 patents-in-suit potentially.

09:25:27 7 I should just mention real quick, there was category
09:25:31 8 on the prior slide called NA. I did re-run these numbers
09:25:35 9 excluding the NA category, and they were still pretty
09:25:38 10 consistent on the order of, I think, 70-30 instead of 74-26.
09:25:46 11 But what we can see is that the vast majority of prescriptions
09:25:51 12 quantitatively aren't covered by the claims of the
09:25:55 13 patents-in-suit and therefore lack nexus.

09:26:44 14 Q Okay. And what overall conclusions did you draw from
09:26:44 15 your analysis of this historical Vascepa prescriptions based
09:26:44 16 on the NDTI data?

09:26:44 17 A Well, think that the ability to analyze this quantitative
09:26:44 18 NDTI data gives us very strong evidence that the marketplace
09:26:44 19 performance of Vascepa is not due to the claims in the
09:26:44 20 patents-in-suit. I mean, we already covered the fact that it
09:26:44 21 hasn't performed well.

09:26:44 22 But even looking at the performance, only a fraction
09:26:44 23 of it, about 25 percent, would potentially even be covered.
09:26:44 24 So that lack of nexus, combined with the poor marketplace
09:26:44 25 performance, is not indicative of commercial success.

09:26:44 1 Q And then in terms of the amount of on-label versus
09:26:44 2 off-label sales -- you've been in court for every trial day,
09:26:48 3 correct?

09:26:48 4 A I have.

09:26:48 5 Q And you heard Dr. Budoff's estimation of the on-label and
09:26:54 6 off-label sales?

09:26:54 7 A I did, yeah. He, I think last week, said that he thought
09:26:59 8 it was more like 85 percent off-label to 15 percent
09:27:04 9 potentially being covered by the patents-in-suit.

09:27:07 10 And, you know, that's -- that may be his experience,
09:27:10 11 and that certainly is going to be the experience going forward
09:27:13 12 with REDUCE-IT and the additional labeled indication for
09:27:16 13 people with lower than 500 milligrams per deciliter.

09:27:28 14 Q Mr. Hofmann, did you review any information concerning
09:27:29 15 clinical trials related to treatment of patients with
09:27:30 16 triglyceride levels below 500 milligrams per deciliter?

09:27:35 17 A I did, certainly not in any clinical way, but I think we
09:27:38 18 heard from a number of witnesses last week about the ANCHOR
09:27:45 19 trial as well as the REDUCE-IT trial, both of which are
09:27:49 20 directed to patients under 500 milligrams per deciliter.

09:27:54 21 MR. BARABAS: Then, I'm sorry, if we could go
09:27:56 22 back to DDX 8.13. I'm sorry, I don't believe I moved this
09:28:02 23 into evidence as a summary exhibit. So defendants would
09:28:07 24 request that DDX 8.13 be moved into evidence as a summary
09:28:11 25 exhibit.

09:28:12 1 MR. M. KENNEDY: No objection, Your Honor.

09:28:12 2 BY MR. BARABAS:

09:28:14 3 Q And then there are two documents listed at the bottom,
09:28:18 4 DX 2067 and DX 1607. Mr. Hofmann, are these the documents you
09:28:24 5 relied on to prepare these summary exhibits?

09:28:26 6 A Yes, that's the NDTI data.

09:28:29 7 MR. BARABAS: And subject to plaintiffs' having
09:28:31 8 a chance to redact those documents, defendants request that
09:28:34 9 those documents also be moved into evidence.

09:28:37 10 MR. M. KENNEDY: No objection, Your Honor.

09:28:37 11 THE COURT: All right. 8.13 is admitted as a
09:28:41 12 demonstrative, and DX 2067 and 1607 are admitted.

09:28:46 13 I don't recall you moving to admit DX 2039 which
09:28:51 14 was the supporting -- I assume the data -- I've seen this
09:28:56 15 chart many times, but I assume the underlying data came from
09:29:00 16 it 2039. Did you want to move that in?

09:29:03 17 MR. BARABAS: Yes. Thank you, Your Honor. We
09:29:03 18 would like to move DX 2039.

09:29:04 19 And, Your Honor, to the extent there's any
09:29:05 20 difference between -- in the demonstratives and summary
09:29:09 21 exhibits, I would like to clarify that all the slides we'd
09:29:13 22 move into evidence, would like moved into evidence as summary
09:29:17 23 exhibits pursuant to Rule 1006 of the Federal Rules of
09:29:21 24 Evidence.

09:29:21 25 THE COURT: Any objection, Mr. Kennedy?

09:29:22 1 MR. M. KENNEDY: No objection.

09:29:24 2 THE COURT: All right. That request is granted.

09:29:25 3 And, to be clear, 2039 is also admitted.

09:29:25 4 (Defendants' Exhibits 8.13, 2067, 1607
09:29:30 and 2039 received in evidence.)

09:29:30 5 MR. BARABAS: Thank you Your Honor.

09:29:30 6 BY MR. BARABAS:

09:29:32 7 Q Okay. So I believe, Mr. Hofmann, we have been
09:29:35 8 discussing -- you had just mentioned the ANCHOR trial and the
09:29:38 9 REDUCE-IT trial.

09:29:39 10 Is Amarin able to promote Vascepa based on the
09:29:43 11 ANCHOR trial and the REDUCE-IT trial?

09:29:45 12 A Yeah. So I think we heard, again, a little bit last week
09:29:53 13 about the ANCHOR trial specifically, that it was not approved
09:29:57 14 in terms of a labeled indication, that only the MARINE trial
09:30:02 15 was approved in 2013 for patients with very high
09:30:09 16 triglycerides.

09:30:11 17 But -- and years ago that would mean that you could
09:30:15 18 not promote off-label indications. Certainly, physicians
09:30:18 19 always have their discretion on what they choose to prescribe
09:30:23 20 to their patients, but there were restrictions on what you can
09:30:28 21 promote to physicians that had to be tied to the labelled
09:30:32 22 indication.

09:30:33 23 Amarin undertook the step to fight FDA in court to
09:30:41 24 get permission to promote the ANCHOR trial with certain
09:30:47 25 restrictions, but even though the ANCHOR trial was off-label,

09:30:52 1 they were -- they successfully got permission to promote the
09:30:56 2 ANCHOR trial, which means that they were able to generate, you
09:31:02 3 know, prescriptions associated with promoting the ANCHOR
09:31:06 4 trial, which is evident in the data that we saw, that the vast
09:31:11 5 majority of sales relate to patients under 500 milligrams.

09:31:15 6 Q How does Vascepa's new indication based on the REDUCE-IT
09:31:18 7 trial impact your nexus analysis?

09:31:21 8 A Well, like I said, they -- they've been able to promote
09:31:25 9 the ANCHOR trial with restrictions, but now they have the
09:31:30 10 ability to promote the REDUCE-IT results, and they obtained
09:31:36 11 the labeled indication, and I think we heard from various
09:31:39 12 clinicians last week that that's really going to expand and
09:31:43 13 broaden the use of REDUCE-IT -- or, I'm sorry, the use of
09:31:48 14 Vascepa for patients below 500 milligrams per dose.

09:31:52 15 Q And I think we've heard about H.C. Wainwright a bit in
09:31:56 16 your testimony. Did H.C. Wainwright comment on the importance
09:32:00 17 of the REDUCE-IT trial?

09:32:00 18 A They did. In one of their analyst reports. H.C.
09:32:06 19 Wainwright said that the REDUCE-IT trial and getting the
09:32:09 20 labeled indication was the sole determinate -- those are their
09:32:12 21 words -- of the future value of Amarin.

09:32:14 22 Q Is that important to your analysis?

09:32:17 23 A It definitely does fit into everything else I've studied
09:32:21 24 in terms of the lack of nexus, and certainly undermines what I
09:32:27 25 think we might hear from Dr. Nicholson in terms of future

performance.

What analysts are saying and even Amarin internally is saying is the REDUCE-IT trial is what's driving the future value of this company, and, as we've heard, the REDUCE-IT trial relates to patients that aren't covered by the claims in the patents-in-suit and therefore lack nexus, therefore no commercial success.

Q You stated earlier that Dr. Nicholson doesn't dispute that two thirds of Vascepa prescriptions are being prescribed off-label. How does this impact Dr. Nicholson's discussion of nexus?

A Well, I mean, I think the NDTI data that I studied he studied as well, and, I think, came to similar conclusions that, based on historical data, two thirds of historical use, if not more, are unrelated to the claims of the patents-in-suit.

However, I think he has some discussion that conflates the concept of nexus in a commercial success setting with FDA approval.

Q So how does initial FDA approval of a drug relate to nexus and commercial success?

A Well, I think what we might hear from Dr. Nicholson is that, you know, because the first labeled indication was for patients with greater than 500 milligrams per deciliter, that he can somehow take credit for all future sales of Vascepa,

1 and that -- that's -- again, that conflates FDA approval with
2 looking at nexus.

3 From an economic perspective, nexus is tying the
4 claims of the patents-in-suit to the marketplace performance.
5 If it were the standard that you could just look at initial
6 approval and then take all future indications, all future
7 sales, all future performance of a product, you would have a
8 really economically unsound result because you would be taking
9 credit for actual and future sales that aren't tied to the
10 patents that you're studying and don't show a nexus to the
11 patents that you're studying.

12 Q Okay. Mr. Hofmann, you mentioned earlier that the
13 limited performance of Vascepa is driven by extrinsic factors
14 unrelated to the asserted claims of the patents-in-suit. What
15 are the extrinsic factors to which you were referring?

16 A There's two main categories, marketing and promotion, as
17 well as discounts, rebates, and other incentives.

18 Q Please briefly explain Amarin's marketing and promotional
19 efforts for Vascepa.

20 A So Amarin has undertaken a very extensive and intense
21 marketing campaign with respect to Vascepa. They've used
22 things like direct consumer advertising, detailing, sampling,
23 co-promotion agreements, and we can even study how intense
24 it's been through a measure called Share of Voice.

25 Q Then, Mr. Hofmann, you mentioned earlier that the

09:35:36 1 marketplace performance of Vascepa is driven by the marketing
09:35:39 2 and promotional efforts of Amarin; is that right?

09:35:42 3 A Correct.

09:35:42 4 Q Have you seen evidence that discusses the importance of
09:35:45 5 marketing to the performance of Vascepa?

09:35:47 6 A Yes. So I studied the marketing intensity and importance
09:35:54 7 of marketing both on an qualitative basis based on statements
09:35:58 8 they've made to the public, as well as on a quantitative
09:36:01 9 basis.

09:36:01 10 Q Okay. Now, if we could turn to DDX 8.14, and this slide
09:36:09 11 is entitled "The Importance of Marketing and Promotion to
09:36:12 12 Vascepa." And if we could take those quotes one at a time,
09:36:16 13 Mr. Hofmann.

09:36:17 14 The first quote is,

09:36:19 15 "Our current level of sales and marketing
09:36:24 16 activities for Vascepa is significant."

09:36:27 17 How does that impact your analysis?

09:36:29 18 A This is just a high level quote that is, again, senior
09:36:33 19 management at Amarin telling the investing public how
09:36:38 20 important sales and marketing is for Vascepa, how significant
09:36:41 21 it is.

09:36:42 22 MR. BARABAS: And this quote is found at
09:36:45 23 DX 2057, pin cite 3, and defendants' move DX 2057 into
09:36:51 24 evidence.

09:36:51 25

09:36:51 1 BY MR. BARABAS:

09:36:58 2 Q Okay. The second quote --

09:36:58 3 THE COURT: I'm sorry, Mr. Kennedy, do you have
09:37:00 4 any objection to DX 2057 being admitted, which apparently
09:37:04 5 supports the first quote on this demonstrative?

09:37:09 6 MR. M. KENNEDY: Yeah, I guess the only
09:37:09 7 difficulty I have, I don't know offhand what it is. It's a
09:37:13 8 little hard to not object if it's just a quote on a
09:37:15 9 demonstrative. I mean, maybe if we could lay a little more
09:37:18 10 foundation of how it supports his opinion.

09:37:18 11 BY MR. BARABAS:

09:37:22 12 Q So DX 2057, according to my notes, is the Amarin
09:37:25 13 Corporation PLC fourth quarter 2018 earnings call transcripts.

09:37:30 14 Mr. Hofmann, did you review the Amarin earnings call
09:37:35 15 transcripts?

09:37:35 16 A I did.

09:37:36 17 Q And it's your understanding that this quote is taken from
09:37:41 18 the earnings call transcripts?

09:37:42 19 A Yeah. I think it's in the binder and it's on screen.
09:37:46 20 That's where this quote comes from, is every quarter senior
09:37:49 21 management at Amarin has a call with analysts and talks to
09:37:54 22 them about their performance.

09:37:57 23 And in this earnings call they communicated to the
09:38:03 24 investing community about the importance of the significance
09:38:06 25 of marketing, and that's what I've summarized in the

09:38:08 1 demonstrative.

09:38:09 2 THE COURT: Mr. Kennedy?

09:38:10 3 MR. M. KENNEDY: No objection.

09:38:11 4 THE COURT: 2057 is admitted.

09:38:11 5 (Defendants' Exhibit 2057 received in
09:38:11 evidence.)

09:38:11 6 BY MR. BARABAS:

09:38:15 7 Q Okay. And the second quote on DDX 8.14 is that,

09:38:19 8 "Our ability to succeed lies in the strength

09:38:22 9 of the Vascepa clinical profile and aggressive

09:38:25 10 targeted sales and marketing efforts."

09:38:28 11 And how does that quote impact your analysis,

09:38:32 12 Mr. Hofmann?

09:38:32 13 A Yeah. So I think this one comes from like an internal
09:38:37 14 Amarin e-mail where management within Amarin are talking about
09:38:42 15 their aggressive and targeted sales and marketing efforts.

09:38:46 16 And, again, this is consistent with what I see
09:38:50 17 qualitatively and quantitatively on the importance of
09:38:53 18 marketing.

09:38:54 19 MR. BARABAS: And then so DX -- excuse me,
09:38:57 20 DX 1762, according to my notes, is an e-mail forwarded from
09:38:57 21 Mr. Berg to Mr. Thero regarding generic Lovaza, perception
09:39:07 22 versus reality, and defendants seek to move DX 1762 into
09:39:09 23 evidence.

09:39:10 24 MR. M. KENNEDY: No objection.

09:39:10 25 THE COURT: 1762 is admitted.

(Defendants' Exhibit 1762 received in evidence.)

BY MR. BARABAS:

Q Okay. The third quote we have on DDX 8.14 is, quote, "Samples and co-pay cards have a considerable impact on physicians' prescribing of Vascepa."

How does that quote impact your analysis Mr. Hofmann?

A Yes. So this -- this was an internal Amarin document that talks about their kind of commercial planning and strategy.

And what they are specifically addressing is the importance of, again, two tools, I think, sampling and co-pay cards, which is a form of patient assistance, and so these are specific tools, and the importance of those tools from a marketing perspective which drive the sales of Vascepa.

MR. BARABAS: Okay. That quote is found DX 1773, pin cite 9, and DX 1773 is a document entitled "Amarin Commercial Update." Defendants' seek to move DX 1773 into evidence.

MR. M. KENNEDY: No objection, Your Honor.

THE COURT: 1773 is admitted.

(Defendants' Exhibit 1773 received in evidence.)

MR. BARABAS: Thank you, Your Honor.

BY MR. BARABAS:

Q The fourth quote is,

09:40:23 1 "Elevate Vascepa value with a strong
09:40:26 2 celebrity messenger on national TV and print vehicles
09:40:31 3 - including their social media channels."

09:40:34 4 How does this quote impact your analysis,
09:40:37 5 Mr. Hofmann?

09:40:38 6 A Well, like I said, Amarin has used all the tools in the
09:40:42 7 tool box in terms of marketing, and one of the tools is
09:40:45 8 direct-to-consumer advertising. I think we've all seen
09:40:50 9 pharmaceutical companies advertise on TV.

09:40:52 10 And, specifically, at one point Amarin got a
09:40:55 11 television celebrity to be in TV ads as well as in some of
09:41:02 12 their print vehicles. What that refers to is flyers and stuff
09:41:06 13 that they leave with physicians when detailing or in the
09:41:09 14 offices.

09:41:10 15 And then social media channels, that relates to
09:41:13 16 things like banner ads or FaceBook that target patients to --
09:41:19 17 and they incorporated the celebrity into their outreach.

09:41:26 18 MR. BARABAS: So DX 1772 is entitled "Vascepa
09:41:30 19 Celebrity Brand Campaign," and defendants seek to move DX 1772
09:41:35 20 into evidence.

09:41:36 21 MR. M. KENNEDY: No objection, Your Honor.

09:41:38 22 THE COURT: 1772 is admitted.

09:41:38 23 (Defendants' Exhibit 1772 received in
09:41:41 evidence.)

09:41:41 24 MR. BARABAS: Thank you, Your Honor.

09:41:42 25 If we could turn now, Mr. Gross, to DDX 8.15.

09:41:42 1 BY MR. BARABAS:

09:41:47 2 Q This slide is entitled "Amarin Marketing Spend for
09:41:53 3 Vascepa."

09:41:54 4 And, Mr. Hofmann, with reference to this summary
09:41:58 5 exhibit, did you analyze Amarin's total marketing spend for
09:42:03 6 Vascepa?

09:42:04 7 A Yeah. So, in addition to the qualitative kind of
09:42:09 8 exemplary quotes we just looked at on the last slide, I looked
09:42:12 9 at the numbers, and, based on the product profit and loss
09:42:16 10 statements, was able to analyze how much Amarin spent on
09:42:19 11 marketing and sales related to Vascepa.

09:42:25 12 And in summing those amounts up, it comes to \$575
09:42:30 13 million, more than half a billion dollars, on marketing, and I
09:42:36 14 compared that to what they were able to generate in sales
09:42:39 15 during that same period, which works out to about
09:42:43 16 \$698 million.

09:42:44 17 And then I calculated the percentage of marketing
09:42:48 18 expenses relative to sales, and you can see that 82 cents of
09:42:54 19 every dollar has essentially been spent on sales and
09:42:59 20 marketing, and what this tells me is they've invested very
09:43:02 21 heavily in marketing associated with Vascepa.

09:43:06 22 Q Okay. Mr. Hofmann, on the bottom left of this summary
09:43:10 23 exhibit is a reference to DX 2050, which is entitled
09:43:15 24 "Quarterly Financial Summary Q-1 2013, Q-4 2014."

09:43:20 25 Is that a document you relied upon in preparing this

09:43:23 1 summary exhibit?

09:43:24 2 A It is.

09:43:26 3 MR. BARABAS: Defendants move to admit DX 2050
09:43:31 4 as a -- into evidence.

09:43:33 5 MR. M. KENNEDY: No objection, Your Honor.

09:43:35 6 MR. BARABAS: And defendants --

09:43:35 7 THE COURT: 2050 is admitted.

09:43:35 8 MR. BARABAS: Thank you, Your Honor.

09:43:39 9 And defendants' also move to admit DDX 8.15 into
09:43:42 10 evidence as a summary exhibit.

09:43:44 11 MR. M. KENNEDY: No objection, Your Honor.

09:43:46 12 THE COURT: 8.15 is also admitted as a
09:43:46 13 demonstrative.

09:43:46 14 (Defendants' Exhibits 2050 and 8.15
09:43:50 received in evidence.)

09:43:50 15 MR. M. KENNEDY: Your Honor, if I could just
09:43:51 16 note with 20150, we would like the opportunity to redact.

09:43:54 17 THE COURT: Yes.

09:43:56 18 MR. BARABAS: And, Your Honor, to the extent
09:44:00 19 there's any distinction, we would seek to admit DDX 8.15 as a
09:44:02 20 summary exhibit.

09:44:03 21 THE COURT: I'm sorry, you're also moving
09:44:06 22 DDX 8.15 as a summary?

09:44:08 23 MR. BARABAS: Yeah, as opposed to a
09:44:09 24 demonstrative to the extent there's any difference for your
09:44:12 25 purposes.

09:44:13 1 THE COURT: Well, it's a summary exhibit that's
09:44:15 2 admitted as a demonstrative exhibit, right?

09:44:18 3 MR. BARABAS: Okay. Thank you.

09:44:18 4 BY MR. BARABAS:

09:44:21 5 Q So, Mr. Hofmann, earlier in your testimony you also
09:44:24 6 mentioned detailing. Please explain briefly what detailing of
09:44:28 7 pharmaceutical products is.

09:44:29 8 A Sure. So detailing is a technique, a marketing
09:44:34 9 technique, that is sometimes undertaken by brand sponsors of
09:44:38 10 drugs.

09:44:39 11 What they do is they have sales representatives that
09:44:42 12 will typically physically visit physicians, potential
09:44:47 13 prescribing physicians, provide information about the drug,
09:44:51 14 provide samples to give to patients, provide coupons and
09:44:56 15 patient assistant cards, as well as materials to be left in
09:45:00 16 the office for use of prescribers and patients.

09:45:04 17 It's a -- it's a technique used to drive
09:45:09 18 prescriptions of the product at issue.

09:45:11 19 Q So you mentioned sales representatives. How large is the
09:45:14 20 Amarin sales force for Vascepa?

09:45:16 21 A It's varied over time. I think it started at 275 reps.
09:45:24 22 It's gone down a little bit, then back up.

09:45:27 23 And I think in 2019, they expanded it significantly
09:45:33 24 in anticipation of the REDUCE-IT trial results and additional
09:45:38 25 labelled indication.

09:45:39 1 Q Did Amarin perform all of its own promotional activities?

09:45:43 2 A No. In addition to their internal sales reps, they
09:45:47 3 entered into a co-promotion agreement with a Japanese
09:45:52 4 pharmaceutical company called Kowa, K-o-w-a, Pharmaceuticals.

09:45:57 5 Q Did you see evidence of the importance of the
09:46:00 6 co-promotion agreement to Amarin for Vascepa?

09:46:02 7 A Yes. There was a number of documents in Amarin's files
09:46:06 8 that were produced that talk about the importance of Kowa.

09:46:10 9 MR. BARABAS: So, Mr. Gross, if we could turn to
09:46:12 10 DDX 8.16.

09:46:12 11 BY MR. BARABAS:

09:46:14 12 Q And, Mr. Hofmann, if we could take these quotes one at a
09:46:17 13 time. This exhibit is entitled "The Importance of the
09:46:22 14 Co-Promotion Agreement With Kowa."

09:46:26 15 And the first quote is that,

09:46:28 16 "Kowa's co-promotion efforts are planned to
09:46:31 17 significantly expand our target physician subscriber
09:46:35 18 base and more than double current sales detail
09:46:39 19 frequency, including resumption of details to
09:46:42 20 physicians not currently targeted by Amarin's sales
09:46:45 21 representatives."

09:46:47 22 How does this quote impact your analysis?

09:46:50 23 A So this quote comes from one of those quarterly earnings
09:46:54 24 calls I mentioned, or we discussed a little while ago, where
09:46:57 25 senior management of Amarin is telling the investment

community that they've entered into this agreement with Kowa and that they expect the agreement with Kowa to significantly expand their outreach, their ability to detail to prescribers, which they hope that that additional marketing and co-promotion will generate additional prescriptions for Vascepa.

MR. BARABAS: Okay. And this quote actually comes from DX 2079, pin cite at page 2, which is the Amarin Corporation PLC first quarter 2014 earnings call transcript. Defendants' move to admit DX 2079 into evidence.

MR. M. KENNEDY: No objection.

THE COURT: DX 2079 is admitted.

(Defendants' Exhibit 2079 received in evidence.)

MR. BARABAS: Thank you.

BY MR. BARABAS:

Q The second quote on DDX 8.16 is that, quote,

"As a result, Kowa is very similar with the therapeutic category and have established relationships with many of the high-decile omega-3 prescribers. With expect this dynamic to complement the Amarin sales team efforts and result in accelerated Vascepa prescription growth with initial evidence of their contributions beginning to be visible in the second half of 2014."

Mr. Hofmann, typos aside, how does that quote

09:48:20 1 impact your analysis?

09:48:21 2 A Well, this I think is from the same earnings call, and
09:48:24 3 what senior management is explaining is the rationale, the
09:48:28 4 synergistic benefit of why they partnered with Kowa.

09:48:33 5 Kowa, I think at the time, had been promoting Livalo
09:48:37 6 which is a statin, and I think we heard last week that it's
09:48:40 7 pretty common that patients that present with high
09:48:44 8 triglycerides may also be on a statin, and certainly the
09:48:47 9 prescribers that might prescribe an omega-3 are going to be
09:48:52 10 the same prescribers that are likely to be prescribing a
09:48:56 11 statin.

09:48:56 12 And so senior management is telling the public the
09:49:00 13 importance of -- and synergy of the agreement with Kowa should
09:49:04 14 lead to, you know, the ability to leverage off the existing
09:49:08 15 sales force and relationships that Kowa has with various
09:49:11 16 prescribing physicians.

09:49:13 17 MR. BARABAS: So, Mr. Gross, if we could turn to
09:49:15 18 the next slide DDX 8.17, and this slide is entitled "Market/
09:49:22 19 Performance Co-Promote Target Type."

09:49:22 20 BY MR. BARABAS:

09:49:25 21 Q And, Mr. Hofmann, please describe what is shown on this
09:49:28 22 slide.

09:49:29 23 A Sure. This isn't the slide I necessarily prepared, this
09:49:33 24 is something from Amarin internal documents. This was
09:49:36 25 something that I thought was worth pointing out in terms of --

09:49:41 1 the last slide was more about the announcement of the
09:49:44 2 agreement with Kowa. This slide shows how they were
09:49:48 3 internally assessing the effectiveness of that co-promotion
09:49:53 4 agreement.

09:49:54 5 And so the oval there, and the call-out box, if you
09:49:58 6 will, is Amarin looking at new prescriptions and total
09:50:04 7 prescriptions, in particular, for the situations where Kowa
09:50:09 8 has been involved, and what we can see is pretty high double
09:50:13 9 digit growth in prescriptions since the relationship with
09:50:19 10 Kowa, the co-promotion agreement with Kowa began.

09:50:23 11 MR. BARABAS: Okay. And, for the record, on the
09:50:24 12 bottom left of that slide there, it's DX 1776, which is the
09:50:28 13 Amarin sales and marketing update that I believe has been
09:50:33 14 already admitted into evidence, and that's pin cite 21.

09:50:38 15 THE CLERK: It is not.

09:50:40 16 MR. BARABAS: Thank you.

09:50:40 17 THE CLERK: I don't show it being in evidence.

09:50:42 18 THE COURT: I don't see it as being admitted.

09:50:45 19 Is there any objection to its admission?

09:50:46 20 MR. M. KENNEDY: No objection, Your Honor.

09:50:46 21 THE COURT: All right. 1776, to the extent it
09:50:48 22 hasn't been admitted, is admitted.

09:50:48 23 (Defendants' Exhibit 1776 received in
09:50:53 evidence.)

09:50:53 24 MR. BARABAS: Thank you, Your Honor.

09:50:53 25

09:50:53 1 BY MR. BARABAS:

09:50:55 2 Q Mr. Hofmann, you mentioned that another form of marketing
09:50:57 3 and promotion for Vascepa is Share a Voice. What is Share a
09:51:02 4 Voice?

09:51:02 5 A Well, Share a Voice is a way to measure marketing
09:51:06 6 intensity.

09:51:07 7 What it represents is a way of looking at the amount
09:51:10 8 of dollars spent by a company on a particular product relative
09:51:16 9 to the amount spent by other products with which it completes
09:51:21 10 and then expressing that as a percentage.

09:51:23 11 It basically measures how intense or how much more
09:51:28 12 is being spent on one product versus others in the
09:51:32 13 marketplace, how much shouting there is on those products.

09:51:35 14 MR. BARABAS: And, Mr. Gross, if we could turn
09:51:36 15 to DDX 8.18, and this slide is entitled "Promotional Dollar
09:51:43 16 (\$) Spend 2013 to 2017."

09:51:43 17 BY MR. BARABAS:

09:51:45 18 Q And, Mr. Hofmann, please explain your analysis of Share a
09:51:50 19 Voice with reference to this demonstrative.

09:51:52 20 A So, once again, I went to IQVIA. IQVIA is the data
09:52:00 21 aggregator that's regularly used in the pharmaceutical
09:52:04 22 industry.

09:52:04 23 And they, in addition to the other things that they
09:52:07 24 track that we've analyzed, they will also track marketing
09:52:11 25 spending by product, and the data that was available was from

2013 to 2017, so that's from Vascepa launch until 2017, and it's expressed in dollars.

It collects information on direct-to-consumer advertising, on detailing, on sampling, on journal advertising.

And then I took those dollars, the amounts that were spent to Vascepa, compared those to Lovaza and some of the other triglyceride-lowering products that were on the market, and expressed as a percentage how much the Share a Voice was for Vascepa in a pay chart relative to others.

And what you can see is that Vascepa spent more. They -- 37 percent of the Share a Voice is with Vascepa, which is more than any other products by more than double digits.

Q And what did you determine from this Share a Voice analysis?

A Well, I mean, this shows that Vascepa was outspending, out-promoting, out-shouting, out-marketing everybody else in the marketplace.

Now, to put this in context, when we look at their market share, which we looked at a little while ago in the data, their prescription share is about three percent, and so they're significantly outsized in their marketing and promotion to the tune of 37 percent, when, for the same period, they've been only able to get three percent market share.

09:53:44 1 So this shows the significant role as a different
09:53:47 2 way to measure the significant investment by Vascepa on a
09:53:53 3 relative basis -- or by Amarin on a relative basis related to
09:53:57 4 Vascepa versus competitors.

09:53:59 5 Q And, Mr. Hofmann, on the bottom left of this summary
09:54:02 6 exhibit is reference to DX 2088 which is entitled "Total
09:54:06 7 Promotional Dollars." Is that a document you relied upon to
09:54:09 8 prepare this summary exhibit?

09:54:10 9 A Yeah, that's the IQVIA marketing data that is the basis
09:54:15 10 for this.

09:54:16 11 MR. BARABAS: And, Your Honor, defendants
09:54:17 12 request to more DX 2088 into evidence.

09:54:20 13 MR. M. KENNEDY: No objection, although, again,
09:54:21 14 we would like the opportunity to redact the underlying
09:54:25 15 exhibit.

09:54:26 16 MR. BARABAS: And defendants also request that
09:54:28 17 DDX 8.18 be admitted into evidence as a summary exhibit.

09:54:33 18 MR. M. KENNEDY: No objection, Your Honor.

09:54:34 19 THE COURT: All right. DX 2088 is admitted and
09:54:39 20 DDX 8.18 is admitted as summary evidence.

09:54:47 21 And I want to clarify that I agree all the
09:54:49 22 summary evidence that I've admitted so far I admitted under
09:54:52 23 Federal Rules of Evidence 1006.

09:54:55 24 MR. BARABAS: Thank you, Your Honor.

09:54:55 25

(Defendants' Exhibit 2088 and 8.18
received in evidence.)

BY MR. BARABAS:

Q Mr. Hofmann, you also mentioned sampling as another
marketing and promotional measure used by Amarin; is that
right?

A That's correct.

Q What is sampling?

A So in prescription pharmaceutical products, sometimes the
brand sponsor will, through detailing, provide samples to
physicians to give to patients when they write a prescription.

So those samples are actual product, so it will be
actual Vascepa. It may be a 7-day pack or a 30-day pack that
they then write a prescription alongside.

And the idea is that if a patient, you know, leaves
the office with a sample in hand, and they can, for free,
start to try the product, then they're much more likely to
fill the prescription is the rationale, that patient
fulfillment is enhanced, and then prescribers are typically
appreciative of having samples, and that really does encourage
both prescribing behavior and patient fulfillment.

MR. BARABAS: Okay. If we could turn to
DDX 8.19, Mr. Gross, and this slide is entitled "The
Importance of Vascepa Sampling."

BY MR. BARABAS:

Q Now, Mr. Hofmann, with reference to this slide, taking

these quotes one at a time, did you see evidence of the importance of Vascepa's sampling program?

A Yeah. So I think this quote is another one of those quarterly earnings calls where senior management of Amarin is telling the investing public that samples have always been important for them. So it's consistent with what I was seeing elsewhere.

MR. BARABAS: And so this first quote is found at DDX -- I'm sorry, excuse me, DX 2085, pin cite page 11, that's the Amarin Corporation PLC, first quarter 2013 earnings call transcript, pin cite page 11.

Defendants move to admit DX 2085 into evidence.

MR. M. KENNEDY: No objection, Your Honor.

THE COURT: 2085 is admitted.

(Defendants' Exhibit 2085 received in evidence.)

BY MR. BARABAS:

Q And then the second quote we have here, Mr. Hofmann, is also from DX 2085, and that states,

"I expect we will continue to see very robust returns from our samples. To date it's been very, very positive with those doctors who are using samples and accessing samples."

How does that quote impact your analysis?

A Well, is, I think, a very clear example of what I was describing generally, that they give away the samples for free

1 with the idea that they hopefully they will get the
2 prescriptions filled, and then that will translate into
3 revenue for Amarin.

4 And what they're saying is we're seeing positive
5 returns on that, that basically it's worth giving away samples
6 because that encourages prescribing behavior and patient
7 fulfillment.

8 Q Mr. Hofmann, would you please summarize your opinions on
9 the marketing and promotion of Vascepa.

10 A Well, I think we've seen a lot of qualitative and
11 quantitative examples that Amarin, since the launch of
12 Vascepa, has invested heavily in every front, and has told the
13 community and used detailing and direct-to-consumer and
14 samples to drive the marketplace performance of Vascepa, which
15 really is unrelated to the claims of the patents-in-suit and
16 undermines the claims of nexus.

17 Q Okay. Mr. Hofmann, I'd next like to discuss discounts,
18 rebates, and other incentives. How, if at all, do these
19 factors drive Vascepa's marketplace performance?

20 A So on top of the dollars and all the stuff we just talked
21 about on marketing, there are financial incentives that Amarin
22 has undertaken in the form of discounts, rebates, and I say
23 other incentives, but it's really patient assistance type
24 incentives, that add an additional layer of what's really
25 hundreds of millions of dollars to drive the sales of Vascepa.

09:59:09 1 Q And are these tools related to the patents-in-suit?

09:59:14 2 A No, I mean, these are -- these are simply tricks of the
09:59:19 3 trade, if you will, that help encourage prescribing behavior
09:59:24 4 and patient fulfillment by using financial tools that have
09:59:27 5 nothing to do with the claims of the patents-in-suit.

09:59:30 6 MR. BARABAS: So, Mr. Gross, if we could turn to
09:59:32 7 DDX 8.20, and this slide is appropriately entitled "Discounts,
09:59:38 8 Rebates, and Other Incentives."

09:59:38 9 BY MR. BARABAS:

09:59:40 10 Q And, Mr. Hofmann, with reference to this demonstrative,
09:59:46 11 please explain your analysis of discounts, rebates and other
09:59:49 12 incentives.

09:59:50 13 A Yeah. So this information comes from, I think, that
09:59:54 14 quarterly spreadsheet that we've talked before, and I
09:59:58 15 summarized it by year here, and this focuses on gross sales
10:00:03 16 with deductions to get to net sales.

10:00:06 17 Those deductions are the types of rebates and
10:00:12 18 discounts and other incentives primarily that are being used
10:00:16 19 to drive the sales of Vascepa.

10:00:20 20 What we see is they've increased every year and in
10:00:24 21 dollars, which is highlighted in yellow, they go from 10
10:00:28 22 million in the year of launch to about a quarter of a billion
10:00:32 23 dollars in 2018, for an grand total of \$631,000,000, which is
10:00:39 24 about half of the total cumulative sales of Vascepa.

10:00:45 25 MR. BARABAS: And then on the bottom left of

10:00:46 1 this summary exhibit is a reference to DX 2050, which is
10:00:51 2 entitled Quarterly Financial Summary Q1 2013 to Q4 2018.

10:00:58 3 If I haven't already sought to admit this into
10:01:00 4 evidence, defendants seek to admit DX 2050 into evidence.

10:01:04 5 MR. M. KENNEDY: No objection, Your Honor.

10:01:05 6 THE COURT: All right. DX 2050 is admitted and
10:01:08 7 DDX 8.20 is also admitted as a summary exhibit.

10:01:08 8 (Defendants' Exhibit 8.20 received in
10:01:12 evidence.)

10:01:13 9 MR. BARABAS: Thank you Your Honor.

10:01:16 10 If we could turn to the next slide, Mr. Gross,
10:01:21 11 DDX 8.21, and this slide is entitled Discounts, Rebates and
10:01:26 12 Other Incentives As Percentage of Gross Sales.

10:01:26 13 BY MR. BARABAS:

10:01:29 14 Q And, Mr. Hofmann, what have you shown in this summary
10:01:35 15 exhibit?

10:01:35 16 A So this takes the data from the last slide which was in
10:01:38 17 dollars, and it expresses it as a line graph in percentages.

10:01:43 18 And I think there's a couple of important take-aways
10:01:46 19 from this slide. We can see that in every year discounts,
10:01:51 20 rebates, and other incentives have grown.

10:01:54 21 They've always been relatively high, 29 percent in
10:01:58 22 year one. Starting in 2017, it got to 50 percent. Now in
10:02:03 23 2018, we're at 53 percent. So that means essentially, 53
10:02:08 24 cents of every dollar that's being sold is being given away in
10:02:13 25 discounts, rebates and other incentives.

10:02:17 1 And, again, this is all on top of the significant
10:02:19 2 expenditures that we saw on marketing and promotion.

10:02:25 3 MR. BARABAS: Your Honor, defendants move to
10:02:28 4 admit DDX 8.21 as summary exhibit.

10:02:32 5 THE COURT: I think --

10:02:33 6 MR. M. KENNEDY: No objection, Your Honor.

10:02:34 7 THE COURT: Didn't I already admit this?

10:02:37 8 MR. BARABAS: You admitted DDX 8.20. I don't
10:02:40 9 know if you admitted DDX 2 --

10:02:40 10 THE COURT: I'm sorry, I put it incorrectly in
10:02:42 11 my notes. Any objection?

10:02:45 12 MR. M. KENNEDY: No objection, Your Honor.

10:02:45 13 THE COURT: All right. DDX 8.20 -- 21 is
10:02:49 14 admitted.

10:02:49 15 (Defendants' Exhibit 8.21 received in
10:02:50 evidence.)

10:02:50 16 MR. BARABAS: Thank you, Your Honor.

10:02:50 17 BY MR. BARABAS:

10:02:53 18 Q Mr. Hofmann, what is the co-pay program that Amarin
10:02:56 19 offers for patients?

10:02:58 20 A Sure. So within these other incentives category would be
10:03:02 21 what are often referred to as co-pay or patient assistance
10:03:06 22 programs.

10:03:07 23 I think probably most of us have had to go to the
10:03:10 24 pharmacy to fill a prescription, and you're asked to pay a
10:03:13 25 co-pay, which is a portion of the cost of the drug, and

1 depending on your insurance coverage and depending on the
2 formulary replacement in the drug, the co-pay amount is going
3 to vary.

4 And what Amarin has done in order to, again, improve
5 patient fulfillment and prescribing behaviors, they subsidize
6 that co-pay cost where basically if the co-pay was going to be
7 \$75 they may pay a portion of that, and so the patient only
8 has to pay a fraction of the actual co-pay, and so you really
9 insulate the patient from the actual cost of the product.

10 Q So if you could please describe the specific co-payment
11 programs that Amarin has offered for Vascepa.

12 A Yeah. I think it's varied over time, but from what I saw
13 in the Amarin documents, and looking at their website today,
14 it started out at, you know, I think, \$75 per month that
15 Amarin would use to subsidize the co-pay to really insulate
16 the patient from the cost in the product.

17 And then at one point they changed to a
18 pay-no-more-than program, which means rather than a fixed
19 amount, that they would subsidize the patient pays no more
20 than \$9 per month, which is almost on par with
21 over-the-counter fish oil.

22 And, you know, it's subject to certain restrictions
23 and caps, but those, those have been the general trend in the
24 co-pay assistance programs.

25 Q What is your overall conclusion based on analyzing

1 discounts, rebates, and other incentives for Vascepa?

2 A Well, I think when you look at the significance of the
3 discounts, rebates and other incentives, and consider them
4 alongside the marketing and promotion, and the fact that there
5 is not -- most of the prescriptions are being written for
6 patients that aren't even covered by the patents, these are
7 strong, strong indicators of a lack of nexus between the
8 marketplace performance of Vascepa, which isn't even all that
9 good, but shows a lack of nexus to that marketplace
10 performance in the claims in the patents-in-suit.

11 Q Mr. Hofmann, I would like to change topics and discuss
12 apportionment. Do you have any other disagreements with
13 Dr. Nicholson's analysis of Vascepa's marketplace performance?

14 A Yeah. I think -- I think one additional point of dispute
15 I have with Dr. Nicholson is he did nothing to address
16 apportionment or the patent landscape with respect to Vascepa.

17 Q And what do you mean by that?

18 A Well, I mean, if you think about it, when we're looking
19 at marketplace performance, and we have a product that's
20 covered by multiple patents, only some of which are at issue,
21 it's economically unsound not to analyze or apportion value to
22 the patents that aren't at issue and to ascribe, you know, the
23 entire value to the patents when -- when there are other
24 patents that aren't at issue.

25 MR. BARABAS: All right. Mr. Gross, if we could

1 turn to DDX 8.22.

2 BY MR. BARABAS:

3 Q And, Mr. Hofmann, I believe you've been in court every
4 day, and this was a demonstrative that came up maybe on the
5 first day, and looking at DDX 2.22, roughly how many patents
6 cover Vascepa?

7 MR. M. KENNEDY: Your Honor, objection.
8 Mr. Hofmann didn't consider any of these patents in his expert
9 report. These were all listed quite recently. So I don't
10 think there's really any basis for him to conduct a purported
11 apportionment analysis with respect to these patents.

12 MR. BARABAS: Your Honor, I'm not asking
13 Mr. Hofmann to conduct an apportionment analysis.

14 He did have the list of Orange Book patents in
15 his expert report. At the time Mr. Hofmann prepared his
16 expert report, the list of patents was not nearly as large as
17 the current list.

18 But I could direct you to the page and the
19 paragraph of the expert report, and it's paragraph 14, where
20 it states that the following patents are currently listed in
21 the FDA's approved drug products with therapeutic equivalents,
22 evaluations, orange book as allegedly covering Vascepa.

23 THE COURT: Do you have the report?

24 MR. BARABAS: Yes, I do.

25 MR. M. KENNEDY: Again, I would point out that a

1 lot of these patents listed now weren't listed at time of his
2 report.

3 So I agree he analyzed the patents that were --
4 or he considered the patents that were listed as of mid '19,
5 but a bunch of these were listed just a couple weeks ago so
6 that's the basis of the objection.

7 MR. BARABAS: And so, Your Honor, my question
8 was, you know, how many patents allegedly cover Vascepa.

9 Obviously, I don't think there's any dispute
10 with Mr. Kennedy that the number of patents that cover Vascepa
11 today is larger than the number that cover Vascepa in 2019.
12 So --

13 THE COURT: So what's your follow-up question
14 then?

15 MR. BARABAS: My question --

16 THE COURT: Because the parties can stipulate to
17 that, that the number of patents now are greater than the
18 number of patents that were identified or available, disclosed
19 in mid 2019. There's no objection to that?

20 MR. M. KENNEDY: Yeah, I mean, this exhibit is
21 in evidence. The Orange Book listing is what it is.

22 I think the issue is if he goes beyond just
23 saying these are the patents that are currently listed. I
24 think that would constitute a new opinion.

25 But if that's all he's going to do, then I --

10:08:58 1 MR. BARABAS: I think that's right, Your Honor.
10:09:00 2 I think that we've established that Mr. Hofmann is an
10:09:02 3 accountant and economist, he's not a scientist, he's not a
10:09:05 4 medical expert, he's not offering any technical opinion
10:09:09 5 regarding the patents-in-suit, so I don't think we have a
10:09:12 6 dispute here.

10:09:13 7 THE COURT: So I don't understand what you are
10:09:15 8 asking.

10:09:16 9 MR. BARABAS: Well, my initial question I think
10:09:18 10 led to the objection is how many patents allegedly cover
10:09:21 11 Vascepa, which I think is an arithmetic exercise.

10:09:27 12 THE COURT: But my point is you don't even need
10:09:29 13 to ask that question if there's a stipulation that the patents
10:09:32 14 listed on this exhibit are what they are.

10:09:36 15 But the objection is to the extent you asked
10:09:40 16 Mr. Hofmann additional questions about patents that were not
10:09:44 17 listed in his report.

10:09:47 18 MR. BARABAS: Okay.

10:09:48 19 THE COURT: So do you plan to do that? If you
10:09:50 20 plan to do that, then I'll need to rule on the objection.

10:09:53 21 MR. BARABAS: I simply -- I guess, my follow-up
10:09:56 22 question is simply there was another exhibit that was shown in
10:09:59 23 court the first day, and we simply -- I simply would like to
10:10:03 24 ask Mr. Hofmann about the five or so -- I guess it's six
10:10:07 25 patents currently in suit, and there's a vast number of

1 additional patents which are listed as covering Vascepa, to
2 make the point that, you know, one group is very small subset
3 of overall the group of patents. That's all I plan to do.

4 MR. M. KENNEDY: I mean, without conceding
5 that's a legally relevant analysis, if that's all he plans to
6 do, I think we can withdraw the objection.

7 THE COURT: So you don't object to him being
8 asked those two questions?

9 MR. M. KENNEDY: No, if he asks how many patents
10 there are and --

11 THE COURT: Well, my point is it's not even
12 necessary if there's a stipulation. Is there a stipulation?

13 MR. M. KENNEDY: I mean, I think the -- I
14 believe DX 2267, which is current Orange Book listing for
15 Vascepa, is in evidence, so if that's --

16 MR. BARABAS: And, actually, Your Honor, I guess
17 we're jumping a bit. When we get to the next exhibit we're
18 going to -- I think the parties have reached agreement and
19 we're going to move that exhibit into evidence as well.

20 THE COURT: All right. So, let me -- let's --
21 would you go back to -- I think it's 2267.

22 You know what, let's make this easy. Since
23 there's no objection, you can ask those two questions.

24 MR. BARABAS: Thank you, Your Honor.
25

10:11:18 1 BY MR. BARABAS:

10:11:19 2 Q So, Mr. Hofmann, with reference to DDX 2.22, roughly, I'm
10:11:26 3 not asking you to count all of them, how many patents cover
10:11:31 4 Vascepa?

10:11:31 5 A Well, there are dozens. This is the Orange Book listing
10:11:34 6 which I think we heard a little bit about last week, where
10:11:38 7 Amarin has reported to FDA these are the number of patents
10:11:42 8 that they believe cover Vascepa.

10:11:44 9 MR. BARABAS: And then if we could turn now,
10:11:46 10 Mr. Gross, to DDX 2.23, and I guess before I go further, if we
10:11:55 11 haven't already officially done this, Your Honor, would move
10:11:58 12 to admit DX 2299 into evidence.

10:12:02 13 MR. M. KENNEDY: No objection, Your Honor.

10:12:03 14 THE COURT: 2229 is admitted.

10:12:03 15 (Defendants' Exhibit 2299 received in
10:12:03 evidence.)

10:12:03 16 BY MR. BARABAS:

10:12:11 17 Q And then, Mr. Hofmann, you were in court the other day
10:12:11 18 when this ven diagram that's entitled "The REDUCE-IT Patents
10:12:20 19 versus Asserted Patents Summary" was put into evidence? And
10:12:20 20 how does this ven diagram relate to your analysis?

10:12:24 21 A Yes, this goes back to the question of apportionment.

10:12:27 22 Essentially what Dr. Nicholson has done is
10:12:30 23 attributed the entire sales and marketplace performance of
10:12:36 24 Vascepa to the six patents that are at issue in this case,
10:12:40 25 those that are represented in the blue circle.

1 He's not done anything to analyze, apportion or
2 study any economic value to be assigned to the patents listed
3 in the green box, those patents that are not at issue in this
4 case.

5 Q Okay. And why is the existence of multiple Orange Book
6 listed patents for Vascepa relevant to an analysis of
7 commercial success and nexus?

8 A Well, from an economic perspective, essentially by taking
9 credit for the entirety of the marketplace performance of
10 Vascepa and tying that or claiming it to these six patents
11 that are at issue here, without ascribing any value or even
12 considering all these other patents that Amarin has told FDA
13 and told the world that they believe cover the product, you
14 get an economically unsound result where you could
15 theoretically take credit for a hundred percent of the sales
16 for the patents-in-suit here, and then take credit for those
17 same sales associated with patents that aren't even involved
18 in this case.

19 Q Okay. Mr. Hofmann, earlier you testified that no more
20 than one-third of Vascepa prescriptions are covered by the
21 asserted claims of the patents-in-suit. So how is
22 apportionment different from the nexus analysis?

23 A I mean, conceptually there's some overlap.

24 What I had talked about before was based on the NDTI
25 and clinical data that is driven by, you know, how patients

1 present and what their conditions are and whether those are
2 covered by the claims of the patents-in-suit.

3 The idea of apportionment from an economic
4 perspective is more so driven by the patent landscape and how
5 I think it's incomplete and unreliable to not study the patent
6 landscape and simply just assume or take credit for the
7 entirety of sales to the patents-in-suit when we have
8 self-reported evidence by Amarin that they believe they have
9 dozens of other patents that cover the same product.

10 Q What value does -- or I should say, excuse me, what
11 value, if any, does Dr. Nicholson attribute to the other
12 Orange Book listed patents that are not asserted in this
13 matter?

14 A None.

15 Q Okay. All right. Mr. Hofmann, if we could turn now just
16 to your summary of opinions and specifically to DDX 8.24, and
17 taking your three opinions just one at a time.

18 What is your first opinion with respect to
19 commercial success and nexus?

20 A So now I've been able to unpack these a little bit from
21 where we started, and I think we can see it's very clear that
22 the historic marketplace performance of Vascepa is not a
23 marketplace success and it's certainly not indicative of
24 commercial success.

25 They've lost money each and every year the product

1 has been on the market and have nearly a billion dollars in
2 cumulative losses.

3 We can also see on a relative basis they've only
4 been able to garner a small 3 percent market share versus
5 other triglyceride-lowering prescription products, also not
6 indicative of commercial success.

7 Q And what is your second opinion with respect to
8 commercial success and nexus?

9 A It's directed to the issue of, I think, Dr. Nicholson's
10 reliance on future marketplace performance and the hazards in
11 doing so.

12 I think that we can see from the documents and
13 information that I showed that the information is wildly
14 disparate and unreliable and speculative.

15 And the Net Present Value calculation that he's
16 undertaken that relies on this unreliable data and speculative
17 data only results in flawed and unreliable information that I
18 don't think provides a reasonable objective basis to determine
19 marketplace success.

20 MR. BARABAS: And now if we could turn,
21 Mr. Gross, to DDX 8.25.

22 BY MR. BARABAS:

23 Q Mr. Hofmann, what is your third opinion with respect to
24 commercial success and nexus?

25 A So, in any event, even though the weak marketplace

1 performance of Vascepa, when one studies nexus, one sees that
2 the vast majority of sales that have happened and
3 prescriptions that have happened are unrelated to the claims
4 of the patents-in-suit and lack nexus, and that's only going
5 to increase the terms of the lack of nexus as REDUCE-IT and
6 the new label indication carry forward.

7 And then getting past that issue, one further sees
8 the extrinsic factors, the very significant and intense role
9 that marketing and promotion have played, and that discounts,
10 rebates, and other incentives have played, all of which shows
11 a lack of nexus with are respect to the marketplace
12 performance of Vascepa and the claims of the patents-in-suit.
13 So from my perspective there's no evidence of commercial
14 success in this case.

15 MR. BARABAS: Thank you, Mr. Hofmann.

16 Your Honor, I have no further questions at this
17 time.

18 THE COURT: Mr. Kennedy, I think this may be a
19 good time for us to take our morning break while we transition
20 to your cross-examination. Why don't we take our morning
21 break at this time.

22 (A recess was taken.)

23 THE COURT: Please be seated.

24 MR. M. KENNEDY: Your Honor, may I proceed?

25 THE COURT: Yes, please.

10:38:05 1 MR. M. KENNEDY: Good morning, Mr. Hofmann. We
10:38:06 2 met last summer at your deposition, but just to remind you, my
10:38:10 3 name is Mike Kennedy. I'll be asking you a few questions
10:38:14 4 today on behalf of Amarin.

10:38:16 5 Mr. Brooks, can we start with Mr. Hofmann's
10:38:21 6 slide DDX 8-3.

10:38:21 7 CROSS-EXAMINATION

10:38:21 8 BY MR. M. KENNEDY:

10:38:25 9 Q And, Mr. Hofmann, you testified this morning that, in
10:38:26 10 your words on the slide, there must be a causal correlation
10:38:29 11 between the unique merit of the claimed invention and the
10:38:33 12 performance of the product, right?

10:38:34 13 A I did.

10:38:35 14 Q Now, just to clarify, you'll agree with me that in order
10:38:39 15 to establish a nexus, the patentee doesn't have to show that
10:38:42 16 the patented feature is the sole cause of the commercial
10:38:44 17 success as opposed to other factors, right?

10:38:47 18 A Yeah, other factors can play a role.

10:38:49 19 Q Yeah. And by "other factors" you understand I mean
10:38:52 20 things like marketing, other patents, features in the prior
10:38:56 21 art, and so forth, right?

10:38:58 22 A Right. But you have to study the significance of the
10:39:01 23 claims of the patents-in-suit versus those other factors.

10:39:05 24 Q Yeah. And just to be clear you haven't offered any
10:39:08 25 opinion concerning how much of a given products' success needs

10:39:11 1 to be caused by the patented feature as opposed to those other
10:39:15 2 or extrinsic factors, correct?

10:39:18 3 A Not in a quantitative percentage way, no, but I think the
10:39:22 4 totality of the evidence, it's pretty clear.

10:39:25 5 Q But you haven't made -- you haven't drawn any lines or
10:39:28 6 done that analysis in a quantitative way or otherwise,
10:39:31 7 correct?

10:39:31 8 A I don't think there is a bright line threshold.

10:39:34 9 Q Just to clarify a few things about your background, you
10:39:37 10 don't have any training in medicine, do you?

10:39:39 11 A No, sir.

10:39:40 12 Q And you have no experience in lipidology, do you?

10:39:44 13 A I don't.

10:39:44 14 Q And no experience in medicinal or pharmaceutical
10:39:48 15 chemistry, correct?

10:39:49 16 A No, sir.

10:39:50 17 Q And you're not person of ordinary skill in the art for
10:39:52 18 purposes of this case, right?

10:39:53 19 A I don't believe so.

10:39:55 20 Q And you've offered no opinions on the prima facie
10:39:59 21 obviousness of the patents-in-suit, correct?

10:40:01 22 A Correct.

10:40:02 23 Q And you have no opinions regarding the existence of any
10:40:04 24 objective indicia of nonobviousness aside from commercial
10:40:09 25 success, correct?

10:40:09 1 A Yeah, like I said at my deposition, my focus is on
10:40:14 2 commercial success. Whether it has implications to other
10:40:17 3 secondary indicia I'll leave to the lawyers.

10:40:20 4 Q Now, one thing, you do a lot of litigation consulting as
10:40:24 5 I think you testified this morning. In fact, in the four
10:40:27 6 years ending in May, when you submitted your expert report,
10:40:31 7 you've testified in deposition, trial, or hearing more than 90
10:40:35 8 times, right?

10:40:35 9 A I don't have it in front of me but that certainly
10:40:39 10 wouldn't surprise me.

10:40:40 11 Q I'll represent to you that you've disclosed 94 instances
10:40:43 12 in the last four years leading up to May 2019. Does that
10:40:46 13 sound about right to you?

10:40:47 14 A Well, I think some of those are duplicative. But --
10:40:50 15 they're not all separate matters, but --

10:40:53 16 Q But you've testified a lot, right?

10:40:55 17 A I have.

10:40:55 18 Q We can quibble about the number, but you do a lot of
10:40:58 19 testifying.

10:40:58 20 A People draw on my knowledge and expertise regularly, yes.

10:41:03 21 Q Now, another thing you do in your job is you consult on
10:41:06 22 valuation and product pipelines for pharmaceutical companies,
10:41:10 23 right?

10:41:10 24 A As well as other industries, but, yes.

10:41:13 25 Q And -- and those functions can sometimes involve making

10:41:17 1 Net Present Value calculations, right?

10:41:20 2 A I would agree.

10:41:21 3 Q And, in fact, you've reviewed Net Present Value
10:41:23 4 calculations your clients prepared for your feedback and input
10:41:26 5 as part of your valuation and product pipeline consulting
10:41:30 6 work, correct?

10:41:31 7 A I have.

10:41:31 8 Q So just to clarify, your dispute with Dr. Nicholson is
10:41:35 9 not that he invented the concept of measuring the commercial
10:41:38 10 value of a pharmaceutical product by Net Present Value, right?
10:41:42 11 That's not your dispute?

10:41:43 12 A Yeah. I mean, I think I said on direct Net Present Value
10:41:47 13 is a measure that is used in certain settings, I just don't
10:41:51 14 find it appropriate here as objective evidence of commercial
10:41:51 15 success.

10:41:56 16 Q So your dispute with Dr. Nicholson is you don't think
10:41:58 17 it's appropriate -- you don't think it's appropriate to use
10:41:59 18 NPV in this particular context, right?

10:42:02 19 A For a variety of reasons, yes.

10:42:06 20 Q Because your view is the commercial success analysis
10:42:08 21 should be entirely backward-looking, right?

10:42:11 22 A Well, I don't know that I would say that. But in this --
10:42:14 23 these facts and circumstances, when we have six years of
10:42:17 24 actual commercial results, and, you know, the way that he's
10:42:22 25 forecast out very long, speculative periods, I don't think

10:42:26 1 it's appropriate.

10:42:27 2 Q Well, in fact, your analysis was entirely confined to
10:42:30 3 Vascepa profit and loss calculations only through 2018,
10:42:34 4 correct?

10:42:35 5 A I had to use the information and data that was available,
10:42:38 6 and that was the information and data that was available.

10:42:42 7 But it wasn't confined to that. I certainly studied
10:42:45 8 and criticized the forward-looking stuff that Dr. Nicholson
10:42:48 9 used, and, then, of course, there's all the opinions that I
10:42:51 10 expressed on lack of nexus.

10:42:53 11 Q But just to be clear, one of your criticisms of
10:42:57 12 Dr. Nicholson is that he used forward-looking stuff, as you
10:43:01 13 put it, at all, that you don't think you should be using
10:43:03 14 forward-looking stuff. All of your information in your
10:43:06 15 analysis was backward-looking, right?

10:43:08 16 A Well, I think, from a marketplace success perspective,
10:43:13 17 yes. I think that the six years and more of actual data we
10:43:17 18 have is the best objective evidence that we have to reach a
10:43:23 19 conclusion, and there's a real hazard in looking at what he's
10:43:27 20 done forward looking.

10:43:27 21 Q So --

10:43:28 22 A In these facts and circumstances.

10:43:30 23 MR. M. KENNEDY: So, Mr. Brooks, can we have
10:43:32 24 DDX 8.7, please.

10:43:32 25

10:43:32 1 BY MR. M. KENNEDY:

10:43:36 2 Q And, Mr. Hofmann, I just had a quick question about this
10:43:41 3 slide. The prescription data that you've captured on this
10:43:44 4 slide is covering both prescriptions that NDTI coded for the
10:43:50 5 over 500 population, as well as under 500?

10:43:57 6 A Yes, sir.

10:43:58 7 Q Now, let's talk about the analysts' reports for a second.
10:44:01 8 You understand that Dr. Nicholson relied on several analysts'
10:44:04 9 reports in performing his NPV calculation, right?

10:44:08 10 A Yeah, I think there were five.

10:44:10 11 Q Yeah. And your testimony focused almost entirely on the
10:44:13 12 report by Wainwright, correct?

10:44:15 13 A Well, I think that was such an egregious outlier, I used
10:44:20 14 that as example, but I discussed the others as well in his
10:44:23 15 Exhibit 2.

10:44:23 16 Q Now, but, in any event, all the analysts' reports that
10:44:26 17 Dr. Nicholson looked at and that you reviewed as well, those
10:44:29 18 all came out earlier than December 2019, right?

10:44:32 19 A Yeah, that's correct.

10:44:34 20 Q And since you've been in court for most or all the trial,
10:44:38 21 you understand that in December of 2019, Amarin gained a new
10:44:42 22 indication for Vascepa, what we've been calling the REDUCE-IT
10:44:45 23 indication, right?

10:44:46 24 A Yeah. They were certainly anticipating and hoping for
10:44:49 25 that, but, yes, that's when it was officially approved and

10:44:55 1 added to the label.

10:44:56 2 Q So at time that you and Dr. Nicholson both did your
10:44:58 3 expert reports, the REDUCE-IT trial had read out, but Amarin
10:45:02 4 did not yet have the REDUCE-IT indication, correct?

10:45:04 5 A That's correct. But the analysts' reports discussed
10:45:06 6 REDUCE-IT extensively.

10:45:08 7 Q Yes. But, in your view, the use of market projections
10:45:11 8 for an indication that has not been FDA approved does not
10:45:15 9 provide evidence of marketplace success as any such reliance
10:45:19 10 on projections is inherently speculative and unreliable,
10:45:23 11 correct?

10:45:23 12 A I mean, I think you have to study each and every
10:45:26 13 situation, but I certainly agree that in this situation that
10:45:32 14 the way that he's relied upon these future projections and
10:45:38 15 done his own projections is speculative.

10:45:41 16 But, in any event, all that value as discussed in
10:45:43 17 the analysts' reports he relies on is related to REDUCE-IT and
10:45:48 18 nonpatented -- things that aren't covered by the
10:45:52 19 patents-in-suit.

10:45:53 20 Q So, Mr. Hofmann, do you understand the question I just
10:45:56 21 asked you was right out of your expert report from the summer
10:46:00 22 2019?

10:46:00 23 A I dont have it in front of me.

10:46:02 24 MR. M. KENNEDY: Okay. So, Mr. Brooks, can we
10:46:05 25 just have DX 1606, page 25, paragraph 48.

10:46:05 1 BY MR. M. KENNEDY:

10:46:18 2 Q And so here, this is the expert report you served in the
10:46:22 3 summer of 2019, right? I think it was May 2019.

10:46:27 4 A It looks to be, yeah. I didn't -- I didn't see the cover
10:46:30 5 or -- but it looks to be, yeah.

10:46:33 6 Q I mean, I could show it to you if you want.

10:46:33 7 A Sure.

10:46:33 8 Q It's your expert report.

10:46:35 9 A No, that's fine, let's move it along, yeah.

10:46:38 10 Q And it says here your opinion was, and one of your
10:46:42 11 criticisms of Dr. Nicholson was that he was relying on expert
10:46:46 12 reports -- or, I'm sorry, analysts' reports at a time where
10:46:49 13 the REDUCE-IT indication had not yet been granted by FDA.

10:46:54 14 Do you remember that?

10:46:55 15 A I do remember that.

10:46:58 16 Q And one of the things you said, if you look at the last
10:47:01 17 five lines of paragraph 48,

10:47:03 18 "The use of market projections for an
10:47:06 19 indication that has not yet been FDA approved does
10:47:09 20 not provide evidence of marketplace success as any
10:47:13 21 such reliance on projections is inherently
10:47:16 22 speculative and unreliable."

10:47:19 23 Do you see that?

10:47:19 24 A In the context of the whole paragraph, sure.

10:47:22 25 Q So you would agree with me that now we're in 2020, Amarin

1 does have the REDUCE-IT FDA approval, does that change your
2 opinions concerning commercial success?

3 A Not at all. I mean, I think that -- to put it in
4 context, we know that they tried to get the ANCHOR indication
5 on-label and were unsuccessful.

6 So in May, when I wrote my report, although people
7 were very bullish and hopeful that REDUCE-IT would get
8 approved, we don't know until it happens. But I think the
9 analysts were definitely counting on REDUCE-IT in the reports
10 he relied on.

11 Q So let's talk about the forecast a little bit more. And
12 I think you referred to some of these analysts' forecasts
13 as -- I think you called them hopes, dreams, or aspirations;
14 is that right?

15 A Correct.

16 Q And one of the reasons you don't think Dr. Nicholson
17 should have relied on them is that these forward-looking
18 forecasts are nothing more than aspirations? Is that a fair
19 summary of your direct testimony?

20 A I mean, we don't need to bog down on adjectives, but I
21 wouldn't saying nothing more than aspirations.

22 Like I said, on direct, people are in good faith
23 doing their best to predict the future, but we know that the
24 market can be very complex and dynamic and so often times they
25 don't come to pass.

10:48:44 1 Q Would it surprise you to learn that Hikma, one of
10:48:49 2 companies on whose behalf you're testifying, has very recently
10:48:52 3 expressed an aspiration about the market size of Vascepa going
10:48:57 4 forward?

10:48:57 5 A That wouldn't surprise me, no.

10:48:59 6 MR. M. KENNEDY: Mr. Brooks, let's look at
10:49:02 7 PX 1218, please.

10:49:02 8 BY MR. M. KENNEDY:

10:49:05 9 Q And, Mr. Hofmann, I'll represent to you this is a
10:49:11 10 document on Hikma -- is on Hikma's website from January 2020,
10:49:14 11 and you work in the life sciences industry. Have you heard of
10:49:18 12 the JP Morgan Conference?

10:49:20 13 A I have.

10:49:20 14 Q And so you understand that's a big investor conference in
10:49:25 15 San Francisco every January?

10:49:26 16 A I do.

10:49:26 17 MR. M. KENNEDY: And let's go, Mr. Brooks, to
10:49:36 18 page 12 of this exhibit.

10:49:36 19 BY MR. M. KENNEDY:

10:49:36 20 Q And this is where Hikma is telling the marketplace that
10:49:39 21 they're developing a pipeline of complex products to drive
10:49:44 22 future growth.

10:49:45 23 Do you see that?

10:49:45 24 A I do.

10:49:46 25 Q And do you see the product that's listed number four on

10:49:49 1 their list of their generic paragraph 4 pipeline?

10:49:51 2 A I do.

10:49:51 3 Q And do you happen to notice that Hikma is telling the
10:49:55 4 marketplace that Vascepa has a current U.S. market size of
10:50:00 5 \$752,000,000?

10:50:02 6 A Yeah, I think I saw this over the weekend.

10:50:08 7 And what -- it seems to me they're doing what is
10:50:09 8 often done by generics is they're identifying -- you know, you
10:50:14 9 can see there's footnote that says IQVIA U.S. that's
10:50:20 10 essentially the trailing 12 months for October 2019.

10:50:24 11 That's gross sales so that doesn't reflect any of
10:50:27 12 the discounts, rebates, or other incentives, and they're just
10:50:30 13 simply summarizing at a high level the market size according
10:50:33 14 to the data aggregator IQVIA on a gross basis.

10:50:38 15 Q So you're not saying that Hikma is putting out
10:50:40 16 misinformation into the marketplace though are you?

10:50:42 17 A No, but they're not -- I mean, this isn't designed to
10:50:49 18 look at how much of the sales relate to which indication or
10:50:50 19 anything. It's just simply total gross sales according to
10:50:54 20 IQVIA that doesn't reflect all the discounts and other things
10:50:59 21 that I talked about on direct.

10:51:00 22 Q But I think a minute ago you said that the analysts'
10:51:02 23 reports that we've looked at were, you know, people in good
10:51:06 24 faith trying to arrive at the best estimate they could, right?

10:51:09 25 A Yeah. I think there's -- I hope that's what they're

10:51:13 1 doing, sure.

10:51:13 2 Q And just like you hope that the company on whose behalf
10:51:16 3 you're testifying is making a good faith estimate of the size
10:51:19 4 of the Vascepa market as of this month.

10:51:21 5 A They're just creating awareness of the data that's out
10:51:25 6 there on total market size.

10:51:27 7 MR. M. KENNEDY: Mr. Brooks, can we have
10:51:30 8 DDX 821, please.

10:51:30 9 BY MR. M. KENNEDY:

10:51:34 10 Q So, Mr. Hofmann, this is where you were talking about
10:51:36 11 discounts, rebates, and other incentives. Do you remember
10:51:39 12 that testimony from direct?

10:51:41 13 A I do.

10:51:41 14 Q And I take it that your opinion is that this is too much
10:51:45 15 to support a finding of commercial success, a rate of 29 to
10:51:50 16 53 percent?

10:51:50 17 A I don't think I said it that way. I said that this
10:51:54 18 extrinsic financial factor, alongside the marketing and
10:51:59 19 alongside the fact that the vast majority of sales aren't
10:52:03 20 covered by the patents-in-suit really undermines any potential
10:52:08 21 claim of nexus.

10:52:09 22 Q But you'll agree with me the level of discounts, rebates,
10:52:12 23 and other incentives as a percentage of gross sales could be
10:52:15 24 higher than zero consistent with a pharmaceutical product
10:52:18 25 being a commercial success, right?

10:52:21 1 A Yeah, I would not expect discounts, rebates, and other
10:52:26 2 incentives to be zero in pharma.

10:52:26 3 Q So you think a commercially successful product could have
10:52:27 4 more than zero discounts, rebates and other incentives, right?

10:52:32 5 A I don't -- I don't disagree with that no.

10:52:36 6 Q But 29 to 53 percent over a period years, in your view,
10:52:41 7 that's too high?

10:52:42 8 A Well, again, I think I'm looking at this alongside the
10:52:45 9 other extrinsic factors and the lack of prescriptions being
10:52:50 10 written for claims in the patents-in-suit.

10:52:52 11 These are growing, they're significant, and, you
10:52:56 12 know, I'm not making that opinion in a vacuum, I'm looking at
10:53:01 13 alongside the Amarin documents.

10:53:04 14 MR. M. KENNEDY: Let's go, Mr. Brooks, to
10:53:07 15 DDX 8-6, please.

10:53:07 16 BY MR. M. KENNEDY:

10:53:12 17 Q And, Mr. Hofmann, this is your calculation or your
10:53:14 18 depiction, anyway, of various financial metrics for Vascepa,
10:53:18 19 and I would like to direct your attention to the net product
10:53:22 20 sales.

10:53:22 21 Now, when we say net product sales, that backs out
10:53:25 22 the discounts, rebates, and other incentives, right?

10:53:28 23 A That's correct. That's after those.

10:53:29 24 Q And you probably don't agree with me that the sales are
10:53:33 25 significant, but you'll at least agree that Vascepa's net

10:53:37 1 product sales have been growing from 2013 to 2018, correct?

10:53:41 2 A They have, but at a great cost.

10:53:43 3 Q But they're growing. And, in fact, if you do the math,
10:53:48 4 Vascepa's net product sales have increased -- the annual net
10:53:51 5 product sales have increased about eight fold from 2013 to
10:53:55 6 2018, correct?

10:53:56 7 A Roughly, sure.

10:54:00 8 Q Yeah. Just a few general questions about the branded
10:54:05 9 versus generic pharmaceutical industry.

10:54:09 10 Branded pharmaceutical companies have different cost
10:54:12 11 structures compared to generic companies, right?

10:54:16 12 A They do.

10:54:16 13 Q And in general branded pharmaceutical products have
10:54:16 14 higher selling prices compared to generic pharmaceutical
10:54:16 15 products, right?

10:54:22 16 A Yes, they actively market where generics --

10:54:24 17 Q And branded products, not just Vascepa, also have higher
10:54:28 18 associated costs, right?

10:54:30 19 A Which costs are you talking about?

10:54:32 20 Q Well, I could ask you which costs you're talking about,
10:54:36 21 because I'm looking at paragraph 42 of your expert report.

10:54:39 22 A Okay. So --

10:54:40 23 Q I'm just asking a high level question. In general,
10:54:42 24 branded products have higher associated costs than generic --

10:54:47 25 A Yeah, sales, marketing, and R&D is going to be greater

10:54:50 1 for brands.

10:54:51 2 Q And branded pharmaceutical companies typically incur
10:55:01 3 significant costs to develop -- I very much apologize.

10:55:01 4 Branded pharmaceutical companies typically incur
10:55:03 5 significant costs to develop and establish the market for a
10:55:05 6 product, right?

10:55:06 7 A Typically, yes.

10:55:07 8 Q And generic companies typically don't incur such costs,
10:55:13 9 right?

10:55:13 10 A No, they rely on automatic substitution.

10:55:19 11 Q Now, you're generally familiar with the concept of a
10:55:23 12 lifecycle for a pharmaceutical product, right?

10:55:26 13 A Certainly varies for every product, but, yes.

10:55:29 14 Q And a product can be marketed to varying degrees at
10:55:33 15 different points of it's lifecycle, correct?

10:55:36 16 A Yes.

10:55:36 17 Q And at the beginning of a products' lifecycle when it's
10:55:39 18 first launched, there may be a high level of marketing
10:55:43 19 activity for that product, right?

10:55:44 20 A I think that can be the case, depends on whether it's
10:55:46 21 follow-on product or something like that.

10:55:49 22 Q And at the beginning of a product's lifecycle when it's
10:55:52 23 launched, you don't disagree that there's more of a need for
10:55:55 24 marketing activity because doctors need to be educated about
10:55:58 25 the product's attributes, right?

10:56:01 1 A Again, it's highly facts-and-circumstances based, but
10:56:03 2 that can be so sure.

10:56:05 3 Q And by attributes, you understand I mean the clinical
10:56:09 4 profile of the branded product that's been brought to market,
10:56:11 5 correct?

10:56:12 6 A Among other things, sure.

10:56:14 7 Q Like its clinical data, its safety profile, and so forth,
10:56:18 8 correct?

10:56:18 9 A As well as, you know, the availability of samples, the
10:56:24 10 availability of coupons, patient assistance, I mean, they're
10:56:29 11 sharing -- all the stuff they're sharing.

10:56:31 12 Q And once a branded product faces generic competition, the
10:56:34 13 branded company will typically cease or curtail significantly
10:56:39 14 any further marketing support, right?

10:56:41 15 A Yeah, I think in more recent years we've seen examples
10:56:44 16 where they will try and continue, but, by and large, I agree
10:56:47 17 with you.

10:56:47 18 Q And you understand that Lovaza was launched as Omacor in
10:56:52 19 2005, right?

10:56:53 20 A Yes.

10:56:53 21 Q And Lovaza went generic in 2014, right?

10:56:57 22 A That's current.

10:56:57 23 Q And when I say the term "went generic," you understand
10:57:00 24 that I mean that generic versions substitutable versions of
10:57:05 25 Lovaza were launched in 2014, correct?

10:57:08 1 A Starting in 2014, yeah.

10:57:10 2 Q And so it's fair to say that in 2013, Lovaza was towards
10:57:13 3 the end of its lifecycle, correct?

10:57:15 4 A I mean -- I guess, sure. In terms of years, I just don't
10:57:21 5 remember the months, but, yeah.

10:57:22 6 Q And -- but you'll agree with me as to 2013, right? 2013
10:57:27 7 was towards the end of Lovaza's product lifecycle?

10:57:30 8 A Yes.

10:57:30 9 Q And in 2013, as we know, Vascepa had just been launched,
10:57:34 10 correct?

10:57:34 11 A It was.

10:57:35 12 MR. M. KENNEDY: Mr. Brooks, let's go to
10:57:39 13 DDX 8-18.

10:57:41 14 And while we do that, Your Honor, I would also
10:57:43 15 like to move PX 1218 into evidence. That was the Hikma
10:57:47 16 presentation I looked at with Mr. Hofmann.

10:57:50 17 MR. BARABAS: No objection, Your Honor.

10:57:51 18 THE COURT: 1218 is admitted.

10:57:51 19 (Plaintiffs' Exhibit 1218 received in
10:57:51 evidence.)

10:57:51 20 BY MR. M. KENNEDY:

10:57:55 21 Q So, Mr. Hofmann, this is your pie chart showing the
10:57:58 22 promotional dollar spend from 2013 to 2017; is that right?

10:58:02 23 A Correct.

10:58:03 24 Q And we just agreed that in 2013 Vascepa had just been
10:58:06 25 launched, so in 2013, it was at the very beginning of its

10:58:10 1 lifecycle, correct?

10:58:11 2 A It was.

10:58:12 3 Q And we've also just agreed that in 2013 Lovaza was
10:58:15 4 towards the end of its lifecycle, correct?

10:58:18 5 A Yes.

10:58:20 6 Q So in your pie chart, DDX 18, you're comparing marketing
10:58:25 7 spend of Vascepa at the beginning of its lifecycle and a
10:58:28 8 branded product, to Lovaza at the end of its lifecycle,
10:58:32 9 correct?

10:58:33 10 A Well, that's -- that's the market dynamic that existed.

10:58:37 11 What I'm showing in this pie chart is that during
10:58:40 12 the entire time Vascepa has been on the market, they've
10:58:45 13 outspent and outshout every other market on the market.

10:58:48 14 It's true that Lovaza curtailed marketing in 2014.
10:58:52 15 But this means that prescribers were hearing more from Amarin
10:58:55 16 than anybody else, yet they were only able to garner 3 percent
10:59:00 17 share.

10:59:00 18 Q Now, you understand on your pie chart most of these other
10:59:03 19 products fall under the general category of fenofibrates,
10:59:07 20 correct?

10:59:07 21 A I would agree.

10:59:08 22 Q And you were here last week, you probably remember some
10:59:20 23 discussion that fenofibrates are other types of TG lowering
10:59:22 24 agents?

10:59:22 25 A That's my understanding, yes.

10:59:22 1 Q And Tricor, Trilipix, and the other branded fenofibrates
10:59:26 2 all lost exclusivity between 2009 and 2013, correct?

10:59:32 3 A That sounds right.

10:59:33 4 Q So by 2013, the fenofibrate drugs were also at the end of
10:59:38 5 their lifecycle, correct?

10:59:38 6 A Right. They were obviously still doing some marketing
10:59:41 7 because it shows up in the data, but, yeah, I would agree with
10:59:44 8 that.

10:59:44 9 Q They were certainly doing some marketing. In fact, if
10:59:46 10 you total up all the fenofibrate drugs on this chart, it adds
10:59:51 11 up to 34 percent, almost as much as Vascepa, correct?

10:59:55 12 A I haven't -- I haven't looked at it that way, but I'll
11:00:00 13 take your word for it. But there are different, you know,
11:00:04 14 products and different sponsors.

11:00:05 15 Q Sure. But even though they'd gone generic, they're still
11:00:09 16 spending a lot of money on marketing, right?

11:00:12 17 A I mean, there's still some money being spent. They
11:00:16 18 haven't -- I'm sure curtailed the marketing, but there is
11:00:20 19 still some money being sent.

11:00:22 20 MR. M. KENNEDY: Mr. Hofmann, thank you very
11:00:24 21 much. I have no further questions.

11:00:26 22 MR. BARABAS: Your Honor, defendants have no
11:00:27 23 redirect and no further witnesses at this time, but we're
11:00:31 24 keeping our case open because we reserve the right to call
11:00:35 25 Amarin's witnesses.

11:00:36 1 THE COURT: All right.

11:00:38 2 MR. BARABAS: And we also reserve the right to
11:00:40 3 make designations.

11:00:41 4 THE COURT: Thank you.

11:00:42 5 Mr. Hofmann, you may step down.

11:00:45 6 THE WITNESS: Thank you, Your Honor.

11:01:20 7 (The witness was excused.)

11:01:20 8 THE COURT: Mr. Sipes and your colleagues, are
11:01:22 9 you ready to move into Plaintiffs' rebuttal case on invalidity
11:01:27 10 and infringement?

11:01:28 11 MR. SIPES: Yes, we are, Your Honor. I defer to
11:01:30 12 my colleague, Mr. Kennedy.

11:01:32 13 MR. M. KENNEDY: Your Honor, plaintiffs call
11:01:34 14 Dr. Carl Peck.

11:01:36 15 And, Your Honor, may we approach to distribute
11:01:39 16 witness binders?

11:01:40 17 THE COURT: Yes, you may.

11:01:42 18 MR. M. KENNEDY: And I believe we have some
11:01:44 19 slides as well.

11:01:45 20 THE COURT: Thank you.

11:01:45 21 CARL PECK, M.D.,
11:01:45 22 called as a witness on behalf of the Plaintiffs,
11:01:45 23 was sworn and testified as follows:

11:02:14 23 THE CLERK: Please state for the record your
11:02:17 24 full name, spell both your first name and your last name.

11:02:24 25 THE WITNESS: I'm sorry, did you ask me a

11:02:26 1 question?

11:02:27 2 THE CLERK: Yes, sir. Please state for the
11:02:28 3 record your full name, spell both your first name and your
11:02:31 4 last name.

11:02:32 5 THE WITNESS: My name is Carl Peck, spelled
11:02:35 6 C-a-r-l, P-e-c-k.

11:02:39 7 MR. M. KENNEDY: Your Honor, may I proceed?

11:02:40 8 THE COURT: Yes.

11:02:40 9 DIRECT EXAMINATION

11:02:40 10 BY MR. M. KENNEDY:

11:02:42 11 Q Good morning, Dr. Peck. Are you currently employed, sir?

11:02:47 12 A I am.

11:02:47 13 Q Where are you currently employed?

11:02:48 14 A I'm employed by a consulting company that I founded
11:02:53 15 called NDA Partners.

11:02:54 16 Q What does NDA Partners do?

11:02:57 17 A NDA Partners is a consulting firm that provides advice to
11:03:03 18 early stage biotechs concerning their drug development
11:03:08 19 programs, that advises in the domain of regulatory
11:03:12 20 requirements, regulations, and clinical trial designs and
11:03:17 21 statistical analyses.

11:03:19 22 Q Do you have any other positions at the moment?

11:03:21 23 A I hold the position of adjunct professor at the
11:03:27 24 University of California in San Francisco.

11:03:29 25 Q What kinds of classes do you teach?

11:03:32 1 A I teach a course that I founded almost ten years ago
11:03:36 2 called the American Course in Drug Development and Regulatory
11:03:40 3 Science. It is a master's level -- executive master's level
11:03:47 4 course in drug development and regulation.

11:03:49 5 Q Have you ever worked at FDA?

11:03:52 6 A I have, yes.

11:03:53 7 Q What position did you hold at FDA?

11:03:55 8 A During 1987 to 1993, I was center director of the Center
11:04:02 9 For Drug Evaluation and Research.

11:04:04 10 Q We'll talk about that a little more in a minute, but for
11:04:08 11 purposes of today is it okay if I refer to the Center For Drug
11:04:12 12 Evaluation and Research as CDER?

11:04:15 13 A Yes, that would be a rough pronunciation of the
11:04:21 14 abbreviation CDER.

11:04:21 15 Q Have you been retained as an expert in this case?

11:04:24 16 A I have.

11:04:24 17 Q By which party?

11:04:26 18 A By Covington Burling on behalf of Amarin.

11:04:29 19 Q Have you ever worked for Amarin in any capacity prior to
11:04:33 20 this case?

11:04:33 21 A No.

11:04:33 22 Q Generally speaking, can you identify your area of
11:04:36 23 expertise.

11:04:38 24 A I believe I'm expert in drug regulation and clinical
11:04:44 25 pharmacology, clinical trials.

11:04:48 1 MR. M. KENNEDY: Mr. Brooks, can we please have
11:04:51 2 PX 1109.

11:04:51 3 BY MR. M. KENNEDY:

11:04:55 4 Q Dr. Peck, do you recognize this document?

11:04:56 5 A I do.

11:04:57 6 Q What is it?

11:04:58 7 A This is the front page of my curriculum vitae.

11:05:02 8 Q And I see your curriculum vitae is dated April 30th,
11:05:08 9 2019. Is PX 1109 substantially current?

11:05:12 10 A Yes, it is.

11:05:12 11 Q Does PX 1109 accurately reflect your education, training,
11:05:19 12 and experience?

11:05:19 13 A Yes, it does.

11:05:20 14 MR. M. KENNEDY: Your Honor, Amarin moves to
11:05:23 15 admit PX 1109.

11:05:25 16 MR. KLEIN: No objection.

11:05:25 17 THE COURT: 1109 is admitted.

11:05:25 18 (Plaintiffs' Exhibit 1109 received in
11:05:25 19 evidence.)

11:05:25 19 BY MR. M. KENNEDY:

11:05:29 20 Q Dr. Peck, have you worked with us to prepare slides to
11:05:32 21 illustrate your testimony today?

11:05:34 22 A Yes, I have.

11:05:35 23 MR. M. KENNEDY: Mr. Brooks, could we have
11:05:39 24 PDX 4-2.

11:05:39 25

11:05:39 1 BY MR. M. KENNEDY:

11:05:40 2 Q Dr. Peck, can you briefly describe your educational
11:05:43 3 background.

11:05:43 4 A I have an undergraduate degree in mathematics and
11:05:46 5 chemistry. After my three years in undergraduate training I
11:05:51 6 took the Fulbright Scholarship and studied physical chemistry
11:05:58 7 at the Technische Hochschule in Germany.

11:06:01 8 I returned in 1964 and undertook a four-year
11:06:07 9 education in medicine and graduated in 1968 from University of
11:06:12 10 Kansas Medical School.

11:06:13 11 Q Did you subsequently practice medicine?

11:06:16 12 A I did.

11:06:17 13 Q Can you briefly describe your medical practice.

11:06:24 14 A During my internship and residency I was in full-time
11:06:28 15 practice taking care of patients, inpatients in a hospital and
11:06:31 16 in clinics.

11:06:32 17 Subsequent to my internal medicine residency, I
11:06:37 18 began to engage in a research career, but during the 20 years
11:06:42 19 that followed, I always spent time with patients, mostly in a
11:06:47 20 clinic, an oncology clinic at Letterman Army Medical Center in
11:06:54 21 the 1970s.

11:06:55 22 And during 1980 to '87, before I went to FDA, I was
11:07:01 23 in Washington, DC, at the Uniformed Services University, I was
11:07:07 24 army colonel at that time, and I attended on the medicine
11:07:12 25 services at Walter Reed Army Medical Center and the Naval

1 National Medical Center one month each year.

2 Q Dr. Peck, have you engaged in medical research?

3 A Yes.

4 MR. M. KENNEDY: Mr. Brooks, can we have
5 PDX 4-4.

6 BY MR. M. KENNEDY:

7 Q And, Dr. Peck, are these examples of the medical research
8 activities or clinical research activities you've undertaken?

9 A Well, these would be the assignments, the posts that I
10 held.

11 Q Did your research focus on any particular field?

12 A Well, after my internal medicine training I became --
13 well, during it, I became very interested in drugs, the action
14 of drugs in humans, therapeutic drugs, and so I was privileged
15 to take a two-year research fellowship at the University of
16 California in San Francisco where I learned versus techniques
17 of designing and analyzing clinical trials.

18 Subsequent to that, the Army assigned me to the
19 Letterman Army Institute of Research in San Francisco where I
20 joined a team in the blood preservation and research program.

21 That lasted until 1980 when I was reassigned to the
22 Uniformed Services University of the Health Sciences in
23 Washington, D.C.

24 During that seven years before I went to FDA, I
25 continued my research. Much of it was concerning

1 pharmacokinetics and predicting blood levels of drugs in
2 humans, designing clinical trials, and analyzing them.

3 Q You mentioned the phrase drug action in humans. Is that
4 called clinical pharmacology?

5 A Yes, clinical pharmacology is a discipline, a research
6 discipline, that focuses on investigations of what drugs do to
7 humans and what humans do to drugs.

8 Q Why is it important for people to study clinical
9 pharmacology?

10 A Well, in order to understand whether a drug can be used
11 safely and effectively, good science has to be applied to
12 evaluate what the actions of such a drug are in humans.

13 It's important to understand what the dose -- you
14 know, what doses are safe and effective and how long they
15 last, how long to use them.

16 And so while there are some animal studies
17 associated with this discipline, it's primarily a discipline
18 that investigates and clinical studies what drugs do to
19 humans.

20 Q I think you mentioned you've been involved in some
21 clinical studies. Approximately how many clinical studies
22 have you been involved in?

23 A Well, that would be hard to estimate, but I would say
24 hundreds.

25 Q Can you think of one you're particularly proud of the

1 work that you did?

2 A I think the multicenter national clinical trial of a new
3 blood preservation research system that we evaluated in the
4 1970s when I was at Letterman Army Institute of Research was
5 probably the most impactful.

6 Q Why?

7 A Well, at the time we started this research, the storage
8 duration of bank blood was about two weeks.

9 Being in the military, we were concerned about the
10 useful life of blood in blood bags once they reached the
11 field, and so at the time only two or three days were left of
12 viable red blood cells in blood bags.

13 But our research -- we basically invented a new
14 blood preservation system that extended the shelf life of red
15 cells from two weeks to six weeks which was a major increment
16 in the availability of drugs both for the military and for the
17 civilian community.

18 Q Have you had teaching experience?

19 A I have.

20 MR. M. KENNEDY: Mr. Brooks, could we please
21 have PDX 4-5.

22 BY MR. M. KENNEDY:

23 Q Dr. Peck, does PDX 4-5 summarize your teaching positions?

24 A Yes, it does.

25 Q What is the Uniform Services University of the Health

11:11:49 1 Sciences?

11:11:49 2 A It's a military medical school located in Washington, DC,
11:11:55 3 across from the National Institutes of Health. It was
11:11:59 4 established in the 1970s to ensure a steady supply of
11:12:04 5 well-trained physicians, career military physicians, be it
11:12:09 6 Army, Air Force, Navy, of service who would be able to serve
11:12:15 7 the medical needs of service members and their families and
11:12:22 8 retirees.

11:12:22 9 Q What subjects did you teach at USUHS?

11:12:27 10 A Well, I established a division of clinical pharmacology
11:12:31 11 and, in addition to a research program, I had the duty of
11:12:36 12 teaching clinical pharmacology to medical students. We had a
11:12:40 13 second year medical course in which I taught the principles of
11:12:45 14 therapeutic decisionmaking.

11:12:46 15 Q What is therapeutic decisionmaking?

11:12:49 16 A When a physician engages with a patient and understands
11:12:56 17 the list or the issues relating to their health, a decision
11:13:04 18 has to be made about how to benefit the patient.

11:13:07 19 When it comes to drugs, there is a structured
11:13:11 20 approach, which I taught, to making the decision about whether
11:13:15 21 or not to treat with a drug, which drug to treat, which dose
11:13:20 22 to use, what duration, what frequency, what to monitor after
11:13:25 23 the patient has begun to take the drug.

11:13:30 24 Q What information as does a physician consult when
11:13:33 25 engaging in therapeutic decisionmaking?

11:13:39 1 A Well, the physician draw upon his medical education and
11:13:42 2 experience, but the primary source is the FDA-approved drug
11:13:45 3 label.

11:13:47 4 In my view, this is the single most reliable source
11:13:53 5 of information about the action of the drugs, of drugs in
11:13:58 6 humans, and it provides a critical resource for making
11:14:04 7 decisions about the drug and how to use it.

11:14:10 8 Q And the drug label is approved by FDA?

11:14:13 9 A Yes, it is.

11:14:13 10 Q So let's come back to your tenure at FDA.

11:14:18 11 Mr. Brooks, could I have PDX 4-6.

11:14:18 12 BY MR. M. KENNEDY:

11:14:22 13 Q And I think you already mentioned that from 1987 to 1993,
11:14:25 14 you were the director of CDER. Can you explain what is CDER.
11:14:29 15 How does it relate to the overall FDA structure?

11:14:33 16 A Well, FDA regulates 25 cents on the consumer dollar, the
11:14:39 17 products that it regulates are drugs, biologics, medical
11:14:44 18 devices, and so forth.

11:14:45 19 The Center For Drugs, so CDER, was at this time and
11:14:49 20 remains the largest of five to seven centers -- there was five
11:14:57 21 when I was there, now there's seven, and its responsibility is
11:15:00 22 the regulation of the research on new drugs, the review and
11:15:05 23 approval of new drugs, and that would include prescription
11:15:10 24 drugs, over-the-counter drugs, generic drugs, and the
11:15:16 25 postmarketing monitoring and surveillance of safety issues

relating to the drugs it has approved.

Q What were your responsibilities as director of CDER?

A I was responsible for all of the activities of the center which included many of the things that I just mentioned.

I hired staff. I made -- I made decisions about budget and organization. I represented the FDA, the Center For Drugs before the Congress and before the public when issues arose that needed explaining.

Q Did you review and comment on the sufficiency of new drug applications, INDs, and ANDAs?

I'm sorry, as part your duties at CDER did you review and comment on the sufficiency of studies supporting NDAs, ANDAs, and INDs?

A Yes, I did. I supervised the physicians and the FDA scientists who were reviewing this information, but on many occasions I inserted myself and undertook the reviews alongside of them and provided input from my areas of expertise.

Q As director of CDER, did your responsibilities include anything related to prescription drug labeling?

A Well, yes, on a daily basis.

Q Can you describe those responsibilities.

A I can. First of all, one of my -- one of the divisions that I was responsible for was a division of prescription drug labeling, but then every division who was evaluating new drugs

1 and evaluating them for approval were involved in activities
2 relating to guidance to manufactures who were drafting the
3 labels and to reviewing and editing and setting standards for
4 the format and content.

5 Q Approximately how many proposed prescription drug labels
6 did you review at CDER?

7 A Well, that would be hard to estimate; hundreds for sure.

8 Q Do you still work with prescription labeling today?

9 A Yes.

10 Q In what way?

11 A When we consult with biotech companies who are developing
12 a new drug, we teach that a good blueprint for the development
13 of a new drug is to begin to draft the drug label because that
14 will, that will reflect the information that they gain from
15 their clinical trials to inform the drug label on the safety
16 and effectiveness and various ways of using the drug.

17 So in our consultations we often look the at first
18 draft, we make comments, we make suggestions. We refer them
19 to the FDA guidances. And we just work with drug labels all
20 the time.

21 Q And this is work that you perform as part of your NDA
22 partner's organization?

23 A That's correct.

24 Q Now, as part of your work since leaving FDA, have you
25 stayed abreast of developments in FDA's regulation of

11:18:49 1 prescription drug labeling?

11:18:50 2 A Yes, I have.

11:18:51 3 Q How do you go about doing that?

11:18:53 4 A Well, being aware that -- that the standards for content
11:19:02 5 and format are an FDA responsibility, I download guidances
11:19:11 6 from the internet from FDA's website. And I review them, of
11:19:17 7 course, and then I explain them to the -- to, you know, our
11:19:20 8 clients.

11:19:20 9 Q And how often do you do that?

11:19:23 10 A Well, of course I check for updates. Most of them are
11:19:30 11 downloaded already so I simply consult them.

11:19:35 12 But basically, it's important to stay abreast of
11:19:39 13 FDA's guidances because they are. They are sometimes
11:19:44 14 updated -- I should say often updated, and there are many of
11:19:48 15 them.

11:19:50 16 MR. M. KENNEDY: Your Honor, Amarin offers
11:19:52 17 Dr. Peck as an expert in FDA regulation of new and generic
11:19:56 18 drugs including prescription drug labeling.

11:19:59 19 MR. KLEIN: No objection.

11:20:01 20 THE COURT: The request is granted. The Court
11:20:03 21 will certify Dr. Peck as FDA -- as an expert in FDA
11:20:09 22 regulations of new and generic drugs including new drug
11:20:13 23 labels.

11:20:15 24 MR. M. KENNEDY: Thank you, Your Honor.

11:20:15 25

11:20:15 1 BY MR. M. KENNEDY:

11:20:16 2 Q So, Dr. Peck, let's start at the beginning. What is a
11:20:19 3 prescription drug label?

11:20:21 4 A A prescription drug label is a document that, at the end
11:20:27 5 of drug development and FDA approval, contains the information
11:20:33 6 that FDA considers to be essential for a licensed physician to
11:20:39 7 make a decision about a drug and how to use that drug.

11:20:43 8 Q And by information essential, do you mean safety and
11:20:46 9 efficacy data?

11:20:47 10 A It would include safety and efficacy data as well as
11:20:50 11 advice on dosage and which condition it would be treating, so
11:20:57 12 forth.

11:20:57 13 Q Dr. Peck, is the label sometimes referred to as a package
11:21:01 14 insert or prescribing information?

11:21:03 15 A Yes, it is.

11:21:04 16 Q Is it okay if -- if I use those three terms
11:21:07 17 interchangeably today?

11:21:08 18 A Yes.

11:21:09 19 Q So who is the intended audience of prescribing
11:21:13 20 information?

11:21:13 21 A The -- primarily it is the -- a licensed practitioner who
11:21:21 22 is licensed to write a prescription or make an order for a
11:21:27 23 drug in a patient.

11:21:28 24 Q Does the FDA regulate the practice of medicine?

11:21:32 25 A No, it does not.

11:21:33 1 Q So what do FDA regulate?

11:21:35 2 A FDA regulates manufacturers.

11:21:41 3 Q Pharmaceutical companies?

11:21:41 4 A Pharmaceutical companies.

11:21:44 5 Q Does FDA intend for approved drug labels to impact
11:21:48 6 physicians' prescribing decisions?

11:21:51 7 A Yes.

11:21:52 8 Q What rule does FDA play generally speaking in the
11:21:57 9 creation of approved prescribing information?

11:21:57 10 A Well, by regulation, FDA has set the standards for the
11:22:04 11 format and content. So this information is publically
11:22:09 12 available through guidances. FDA also explains them in
11:22:16 13 presentations, and I would say that would be the main avenues
11:22:26 14 of how FDA executes its responsibility.

11:22:31 15 Q Does FDA interact with a new drug applicant in the
11:22:35 16 context of reviewing a particular NDA that includes a
11:22:38 17 particular proposed label?

11:22:40 18 A Yes, numerous times.

11:22:43 19 Q And could you just very -- at a high level describe that
11:22:48 20 process.

11:22:48 21 A Well, the drug development process involves discovery and
11:22:56 22 then new -- you know, animal studies and so forth.

11:23:01 23 Q Oh, the let me clarify my unclear question.

11:23:05 24 Does FDA work with the new drug applicant in the
11:23:08 25 context of commenting, revising and arriving at the approved

11:23:15 1 prescribing information for a given NDA?

11:23:17 2 A Well, yes, it does, many times.

11:23:20 3 Q Could you describe that process of working with an
11:23:23 4 applicant on the prescribing information.

11:23:26 5 A Well, I was giving a longer answer than you need, but
11:23:31 6 when an applicant, even before it begins to study in humans,
11:23:35 7 has a draft label. They may discuss that with the FDA in the
11:23:41 8 pre IND meeting to get advice on how they might be able to
11:23:46 9 reach the -- or how -- achieve the elements of that.

11:23:53 10 Throughout the drug development progress there are
11:23:54 11 numerous communications and meetings with FDA between a
11:23:58 12 company, and the drug label or the elements of the drug label
11:24:02 13 are often a principal element of the dialogue.

11:24:07 14 When the applicant considers that it's time, they
11:24:13 15 will file a new drug application, and part of that new drug
11:24:19 16 application will be a draft label.

11:24:22 17 FDA will review that, edit it, require changes.
11:24:29 18 But, in the end, FDA will approve that drug label according to
11:24:36 19 its standards and its agreement that the words in that label
11:24:40 20 represent truthful and adequate and scientifically sound
11:24:49 21 information that will assist the physician or, you know,
11:24:51 22 encourage the physician to use the drug in a safe and
11:24:55 23 effective manner.

11:24:56 24 Q Does FDA require that an approved drug label follow any
11:25:02 25 prescribed structure?

11:25:03 1 A Yes, there is by regulation, and then explained through
11:25:09 2 guidances, a standardized format and content of the -- of the
11:25:15 3 drug label.

11:25:17 4 Q Are there particular parts of a drug label?

11:25:20 5 A Well, the format comprises roughly 18 sections that each
11:25:28 6 are intended to be concisely written to communicate to the
11:25:34 7 prescriber the essential information needed to prescribe the
11:25:43 8 patient -- the drug to the patient in a safe and effective
11:25:47 9 manner.

11:25:47 10 Q Does the full prescribing information also include a
11:25:50 11 summary of its contents?

11:25:52 12 A Yes, it does.

11:25:52 13 Q Is that called anything?

11:25:55 14 A Well, the front page of the drug label I think is called
11:26:02 15 highlights, and so it will include very brief statements
11:26:10 16 reflecting key information from each of the sections, although
11:26:20 17 there is a -- there is a statement at the top of this page
11:26:25 18 that reminds the physician that the full prescribing
11:26:30 19 information, everything in the label, is important and is not
11:26:34 20 limited to the highlights page.

11:26:37 21 Q So you mentioned there's 18 sections in a prescribing
11:26:41 22 information. Which of those sections does FDA consider
11:26:44 23 relevant to a clinician's prescribing decision?

11:26:47 24 A Every single one.

11:26:48 25 Q Does FDA provide any guidance to pharmaceutical companies

11:26:53 1 on how to prepare their labeling?

11:26:55 2 A It publishes written guidances for almost every section
11:27:00 3 of the drug label.

11:27:03 4 Q Are these guidance documents available to the public?

11:27:06 5 A Yes, they are.

11:27:07 6 MR. M. KENNEDY: Mr. Brooks, can we please have
11:27:08 7 PX 573.

11:27:08 8 BY MR. M. KENNEDY:

11:27:16 9 Q Dr. Peck, do you recognize this document?

11:27:18 10 A I do.

11:27:18 11 Q What is it?

11:27:19 12 A This is a guidance, a typical guidance.

11:27:21 13 Q Uh --

11:27:21 14 A This one specifically identifies what FDA requires in
11:27:28 15 terms of format and content for the indications and usage
11:27:32 16 section of the label.

11:27:34 17 Q And just to recap, what is the indications and usage
11:27:38 18 section of the label?

11:27:39 19 A This is a section that concisely describes the condition
11:27:45 20 or disease that the drug is intended to benefit.

11:27:49 21 Q Did you rely on PX 573 in forming your opinions in this
11:27:54 22 case?

11:27:54 23 A I did.

11:27:56 24 MR. M. KENNEDY: Your Honor, Amarin moves to
11:27:58 25 admit PX 573.

11:28:00 1 MR. KLEIN: No objection.

11:28:00 2 THE COURT: 573 is admitted.

11:28:00 3 (Plaintiffs' Exhibit 573 received in
11:28:00 evidence.)

11:28:00 4 BY MR. M. KENNEDY:

11:28:04 5 Q So, Dr. Peck, I notice that PX 573 says it's draft
11:28:10 6 guidance. Should pharmaceutical companies rely on draft
11:28:14 7 guidance?

11:28:14 8 A Yes.

11:28:14 9 Q Why?

11:28:15 10 A Well, as I noted before, FDA's guidance changes slowly
11:28:25 11 over the years, and so whether a guidance has the word draft
11:28:28 12 on or it whether it's absent, the guidance represents FDA's
11:28:34 13 current thinking about the issues related -- you know,
11:28:36 14 described in the guidance.

11:28:39 15 MR. M. KENNEDY: Mr. Brooks, will you please
11:28:41 16 scroll down to where it says July 2018.

11:28:41 17 BY MR. M. KENNEDY:

11:28:45 18 Q Dr. Peck, to your knowledge, is PX 573 the latest version
11:28:49 19 of the guidance issued by FDA concerning the content and
11:28:53 20 format of the indications and usage section?

11:28:56 21 A Yes, I believe it is.

11:28:57 22 Q To your knowledge, does this still reflect FDA's current
11:29:02 23 thinking on this subject?

11:29:02 24 A Yes.

11:29:03 25 MR. M. KENNEDY: Mr. Brooks, could we turn to

11:29:05 1 page 5 of PX 573.

11:29:05 2 BY MR. M. KENNEDY:

11:29:08 3 Q And, Dr. Peck, I'd like to ask you about the passage that
11:29:11 4 is labeled General Principles. In particular, I would like to
11:29:16 5 ask you about the sentence that begins "Other sections of
11:29:19 6 labeling," and this section this sentence reads as follows,
11:29:23 7 quote,

11:29:23 8 "Other sections of the labeling, e.g., dosage
11:29:27 9 and administration, contraindications, warnings and
11:29:31 10 precautions, use in specific populations, as
11:29:35 11 applicable, also provide essential details that
11:29:39 12 enable safe and effective use of a drug, and labeling
11:29:42 13 should be considered in its entirety for individual
11:29:45 14 prescribing decisions."

11:29:52 15 Dr. Peck, is that an accurate statement of FDA's
11:29:54 16 current thinking on the indications and usage section and the
11:29:56 17 other sections of the labeling?

11:29:57 18 A Yes, it is.

11:29:57 19 Q So the passage I just read lists some examples of
11:30:01 20 sections in the prescribing information that provide essential
11:30:04 21 details to enable safe and effective use of the drug. Does
11:30:08 22 the Clinical Study section also provide such essential
11:30:12 23 details?

11:30:13 24 A Well, yes, it does. As reflected in this highlighted
11:30:16 25 statement, FDA advises that the entire label in all sections

1 should be taken into account.

2 Q Why doesn't FDA want companies to put all these essential
3 details in the indications and usage section?

4 A Well, one of the principles that FDA requires is that the
5 label be readable, readily readable, and truly useful to a
6 busy prescriber.

7 So it intends that each of the sections be concise.

8 Throwing everything into the indications and usage
9 section would lead to, you know, a lengthy document that would
10 be very hard to grasp during the busy practice of a
11 prescriber.

12 Q Does FDA require that labeling be drafted with the
13 intention that clinicians consider the labeling in its
14 entirety for their individual prescribing decisions?

15 A Yes.

16 MR. M. KENNEDY: Mr. Brooks, could we have
17 PX 776.

18 BY MR. M. KENNEDY:

19 Q Now, Dr. Peck, do you recognize this document?

20 A Yes, I do.

21 Q What is it?

22 A Well, this is another guidance pertaining to the format
23 and content of the label, and, in this case, it is specific
24 for the clinical studies section of the label.

25 Q I see that towards the bottom that there's a date,

1 January 2006. To your knowledge, is PX 776 the most recent
2 FDA guidance concerning the clinical studies section?

3 A Yes.

4 Q Did you rely on PX 776 in forming your opinions in this
5 case?

6 A I did.

7 MR. M. KENNEDY: Your Honor, Amarin moves to
8 admit PX 776.

9 MR. KLEIN: No objection.

10 THE COURT: PX 776 is admitted.

11 (Plaintiffs' Exhibit 776 received in
12 evidence.)

BY MR. M. KENNEDY:

13 Q At a high level, Dr. Peck, what's the purpose of the
14 clinical studies section of prescribing information?

15 A Its purpose is to provide to the prescriber an
16 understanding of how the drug can be used and how it was used
17 in the clinical trial or clinical trials that formed the basis
18 for approval.

19 MR. M. KENNEDY: Mr. Brooks, can we turn to
20 page 5 of this document, the section entitled "Identifying
21 Studies For Inclusion in the clinical studies Section."

22 BY MR. M. KENNEDY:

23 Q And in particular, Dr. Peck, I would like to ask you
24 about the first sentence of this passage which reads, quote,

25 "The clinical studies section of labeling

11:32:56 1 must discuss those clinical studies that facilitate
11:33:00 2 an understanding of how to use the drug safely and
11:33:03 3 effectively."

11:33:05 4 Dr. Peck, is this consistent with FDA's current
11:33:08 5 view of the purpose of the clinical studies section of a
11:33:11 6 label?

11:33:11 7 A This is FDA's current view.

11:33:14 8 Q And I would like to ask you now about the second sentence
11:33:16 9 which reads, quote,

11:33:19 10 "This is usually accomplished by providing
11:33:22 11 concise, accurate summaries of information from
11:33:26 12 studies concerning a drug's effectiveness and
11:33:29 13 sometimes safety that practitioners consider
11:33:32 14 important to clinical decision-making."

11:33:35 15 I'd like to ask you couple things about that
11:33:38 16 passage. In FDA's view, why is it important for the clinical
11:33:43 17 studies section to be concise.

11:33:46 18 A As explained, busy practitioners need to have a ready
11:33:51 19 source of information that provides essential information that
11:33:55 20 is most relevant to a physician's prescription or order to
11:34:01 21 benefit that patient.

11:34:03 22 Q Now, this passage in the guidance also talks about
11:34:07 23 information that practitioners consider important to clinical
11:34:10 24 decision-making. What does that mean by "important to
11:34:17 25 clinical decision-making"?

11:34:17 1 A A physician when he considers that -- I should say she as
11:34:27 2 well, there are more lady practitioners than men in medical
11:34:31 3 schools these days.

11:34:33 4 It's important to match up the drug with the
11:34:35 5 patient, and it's also important to make a decision about
11:34:42 6 alternate therapies.

11:34:43 7 So the indications and usage section is very brief.
11:34:48 8 It only identifies the condition to be treated. The physician
11:34:53 9 needs additional information to inform and to encourage the
11:35:00 10 proper use of a medicine.

11:35:04 11 Q Now, in forming your opinions in this case, which label
11:35:08 12 did you review?

11:35:10 13 A I reviewed the Vascepa label.

11:35:12 14 Q Do the opinions you'll express today, and you have
11:35:16 15 expressed, apply equally to Defendants' proposed labeling?

11:35:20 16 A Yes, I believe they do.

11:35:21 17 Q And can you briefly explain why.

11:35:23 18 A Well, a side-by-side comparison of the two, you know,
11:35:28 19 leads to a conclusion that they are essentially the same.

11:35:31 20 Q So you were in court last week when Dr. Sheinberg
11:35:35 21 testified; is that correct?

11:35:36 22 A I was.

11:35:36 23 Q And, in particular, were you present in court when
11:35:40 24 Dr. Sheinberg testified that in his opinion the Vascepa label
11:35:44 25 is completely silent with respect to the duration of therapy?

11:35:47 1 A I did hear that.

11:35:49 2 Q Do you agree with Dr. Sheinberg's opinion?

11:35:51 3 A No, I do not.

11:35:52 4 Q So, in your view, if the label isn't silent, which
11:35:57 5 sections of the Vascepa label are relevant to the duration of
11:36:00 6 use of the approved therapy?

11:36:02 7 A Well, there are at least three of them, and those would
11:36:05 8 be the indications and usage, dosage and administration, and
11:36:11 9 the clinical studies section.

11:36:13 10 MR. M. KENNEDY: Mr. Brooks, can we go back to
11:36:16 11 PX 573. And this is the FDA guidance we looked at a few
11:36:22 12 minutes ago concerning the indications and usage section.

11:36:25 13 Mr. Brooks, can we go to page 14, subsection 1,
11:36:30 14 and this subsection is entitled "Situations in Which
11:36:33 15 Limitations of Use Would Be Appropriate."

11:36:33 16 BY MR. M. KENNEDY:

11:36:37 17 Q In this context, Dr. Peck, what is a limitation of use?

11:36:41 18 A Well, a limitation of use would be a -- a communication
11:36:48 19 to the prescriber with respect to some aspect of the use that
11:36:55 20 should be -- should be limited.

11:36:58 21 Q Are such limitations provided from time to time with
11:37:01 22 respect to the duration of use of the drug?

11:37:03 23 A Yes, they are.

11:37:04 24 Q In what circumstances?

11:37:06 25 A Well, when continued therapy provides no more benefit, so

1 let's say the condition is an acute condition, and after a
2 certain amount of time that the condition is cured, or
3 sufficiently benefitted.

4 Another instance is if continued use of a drug
5 causes a safety issue, then there would be a limitation
6 indicated there as well.

7 Q What's the purpose, in general of this subsection of the
8 FDA guidance about the indications and usage section?

9 A Well, it's to list those critical limitations that FDA
10 considers crucial for safe and effective therapy in the
11 patient.

12 MR. M. KENNEDY: Can we go now, Mr. Brooks, to
13 subsection C, starting on page 15 and going to 16.

14 And the heading of subsection C is "Drugs With
15 Dose Duration Or Long-Term Use Considerations."

16 BY MR. M. KENNEDY:

17 Q And, Dr. Peck, am I correct that this is still part of
18 the limitation of use portion of the FDA guidance?

19 A Yes, it is.

20 Q I'd like to ask you couple questions about the first
21 sentence here which reads, quote,

22 "If information on limitations of use or
23 uncertainty about anticipated benefits is relevant to
24 the recommended dosing intervals to appropriate
25 treatment duration when treatment should be limited,

11:38:37 1 or to any dosage modification, the indications and
11:38:42 2 usage section must include a concise description of
11:38:45 3 the information with a reference to the more detailed
11:38:48 4 information in the dosage and administration
11:38:50 5 section." Unquote.

11:38:52 6 Dr. Peck, does this reflect FDA's current
11:38:57 7 thinking on when the indications and usage section of a label
11:39:01 8 must limit the duration of use of a drug?

11:39:04 9 A Yes.

11:39:04 10 Q When FDA has determined that there's a safety or efficacy
11:39:08 11 reason to limit the duration of use of a drug, must that
11:39:11 12 information be included in the indications and usage section?

11:39:14 13 A Yes.

11:39:14 14 Q I would also like to ask you about the next sentence, and
11:39:21 15 this sentence reads as follows:

11:39:23 16 "Under these circumstances, information about
11:39:26 17 important dose or duration considerations, such as
11:39:30 18 how long a drug can safely be used or uncertainty
11:39:34 19 about the risks and benefits of treatment beyond a
11:39:37 20 certain period, e.g., long-term cumulative toxicity,
11:39:42 21 should be included as a limitation of use."

11:39:44 22 Does this also represent FDA's current thinking?

11:39:47 23 A Yes, it does.

11:39:48 24 Q If FDA had concerns with how long a drug can be safely
11:39:52 25 used, should that be reflected in a limitation of use in the

11:39:56 1 indications and usage section?

11:39:58 2 A It must be.

11:39:59 3 Q And if FDA had concerns about the uncertainty of the
11:40:02 4 risks and benefits of treatment beyond a certain period,
11:40:06 5 should that be reflected in a limitation of use --

11:40:08 6 A Yes.

11:40:09 7 Q -- in the indications and usage section?

11:40:11 8 Now, do you recall Dr. Sheinberg testifying that in
11:40:14 9 his opinion Vascepa is approved only to get TGs below
11:40:20 10 500 milligrams per deciliter, and that using Vascepa to
11:40:23 11 maintain TGs' below 500 milligrams per deciliter would be an
11:40:27 12 off-label use. Do you remember that testimony?

11:40:30 13 A Yes, I do.

11:40:30 14 Q Do you agree with Dr. Sheinberg?

11:40:32 15 A I do not.

11:40:33 16 Q Now, if Dr. Sheinberg were correct that FDA approved
11:40:37 17 Vascepa only to get TGs below 500 and not to maintain them
11:40:42 18 below 500, would there be a duration of use specified in the
11:40:46 19 indication and usage section?

11:40:47 20 A Yes, there would be.

11:40:48 21 Q Now, on the other hand, if FDA approved Vascepa to reduce
11:40:53 22 triglycerides and maintain that reduction for the long-term,
11:40:57 23 would there be a duration of use specified in the indications
11:41:00 24 and usage section of the Vascepa label?

11:41:02 25 A No.

11:41:03 1 Q Now, does the indications and usage section of the
11:41:06 2 Vascepa label limit the duration of use of Vascepa?

11:41:09 3 A No, it does not.

11:41:10 4 Q In your opinion, is Vascepa approved by FDA for long-term
11:41:14 5 use?

11:41:14 6 A Yes.

11:41:15 7 MR. M. KENNEDY: Mr. Brooks, could we go to
11:41:17 8 page 16, please.

11:41:17 9 BY MR. M. KENNEDY:

11:41:19 10 Q And I'm looking at the first full paragraph, and I would
11:41:22 11 like to ask you a couple of questions about the first sentence
11:41:25 12 here which reads, quote,

11:41:27 13 "It is generally not necessary to limit
11:41:30 14 duration of use in the indications and usage section
11:41:34 15 unless such a limited duration is essential to ensure
11:41:37 16 the safe and effective use of the drug," unquote.

11:41:41 17 Is this sentence consistent with your
11:41:43 18 understanding of FDA's current thinking?

11:41:46 19 A Yes.

11:41:46 20 Q Now, I would like to ask you about the next passage, and
11:41:54 21 this passage reads as follows, quote,

11:41:57 22 "If clinical trials evaluated the
11:42:00 23 effectiveness of a drug for a chronic condition only
11:42:03 24 in short-term trials of sufficient duration to
11:42:06 25 support such an approval, e.g., drugs for major

depressive disorder or hypertension, but the drug is indicated for long-term use due to the chronic nature of the condition, and because there's no known or anticipated safety or efficacy concern from continued use, a description of the duration of use from the clinical trials or information about the lack of longer term data generally should not be included in the indications and usage section. Information on the length of the clinical trials should instead be discussed in detail in the clinical studies section of the labeling," unquote.

Dr. Peck, is this passage consistent with your understanding of current FDA thinking on the matter?

A Yes.

Q Now, if a drug is approved for a chronic duration based on a short-term trial, is it FDA's position that the clinical studies section should reference the length of that trial?

A Would you repeat that, please?

Q Sure. Now, in view of this guidance that we've been looking at, if a drug is approved for a chronic indication based on a short-term trial, is it FDA's position that the clinical studies section should reference the length of that trial? The clinical study section --

A The clinical study section, yes.

Q Is this how the Vascepa label is written?

11:43:28 1 A Yes, it is.

11:43:30 2 MR. M. KENNEDY: Mr. Brooks, can we go to
11:43:35 3 PX 572.

11:43:35 4 BY MR. M. KENNEDY:

11:43:36 5 Q Dr. Peck, do you recognize PX 572?

11:43:40 6 A Yes.

11:43:40 7 Q What is it?

11:43:41 8 A It as another guidance or -- unless we've seen this
11:43:46 9 before. This is the dosage and administration section
11:43:50 10 guidance for the label.

11:43:52 11 Q And what -- at a very high level, what is the purpose of
11:43:56 12 the dosage and administration section of an approved label?

11:43:59 13 A Its purpose is to provide a concise information to the
11:44:09 14 physician, encouraging a particular dosage, perhaps a
11:44:14 15 frequency of dosage, duration of dosage when appropriate, and
11:44:20 16 any other -- any limitations with respect to dosage.

11:44:24 17 Q And what's the purpose of this particular guidance?

11:44:27 18 A Well, it's to inform manufacturers on how to write or
11:44:35 19 draft this section of the label.

11:44:37 20 Q Did you rely on PX 572 in forming your opinions in this
11:44:41 21 case?

11:44:41 22 A I did.

11:44:42 23 MR. M. KENNEDY: Your Honor, Amarin offers
11:44:44 24 PX 572 into evidence.

11:44:45 25 MR. KLEIN: No objection.

11:44:46 1 THE COURT: 572 is admitted.

11:44:46 2 (Plaintiffs' Exhibit 572 received in
11:44:49 evidence.)

11:44:50 3 MR. M. KENNEDY: Mr. Brooks, can we have page 5
11:44:53 4 of PX 572, please. There should be a section entitled Basic
11:44:57 5 Dosing Information, if you'd just blow that up.

11:44:57 6 BY MR. M. KENNEDY:

11:45:00 7 Q Dr. Peck, what is the purpose of this portion of the FDA
11:45:03 8 guidance on dosage information?

11:45:06 9 A It's to guide the manufacturer on what specific
11:45:11 10 information regarding dosage should be included.

11:45:15 11 Q Well, it says the section must include the following
11:45:18 12 information. In this context, is there a difference between
11:45:21 13 must and should?

11:45:22 14 A In my view, yes. This is a requirement.

11:45:26 15 Q If we could scroll down to the final paragraph of this
11:45:30 16 section. And I would like to ask you a couple questions about
11:45:37 17 the first sentence of this paragraph which reads as follows:

11:45:41 18 "In describing the dosage range and duration,
11:45:44 19 if it is known that a drug provides no additional
11:45:48 20 benefit above a certain dose or beyond a certain
11:45:51 21 duration of use, that dose or duration must be
11:45:54 22 identified."

11:45:55 23 Is what I just read consistent with FDA's
11:45:59 24 current thinking about the dosage and administration section?

11:46:03 25 A Yes.

11:46:03 1 Q So if it's known that the drug provides no benefit past a
11:46:09 2 certain duration, would the dosage and administration section
11:46:09 3 of the label have to identify that duration?

11:46:11 4 A Yes.

11:46:11 5 Q And if the dosage and administration section does not
11:46:15 6 identify a duration of use, does that mean that the drug's
11:46:20 7 benefit is not thought to cease after a particular time
11:46:24 8 period?

11:46:25 9 A In my view, yes.

11:46:26 10 Q Now, Dr. Peck, can you explain the -- let's highlight --
11:46:32 11 withdraw that. Let's go to this next sentence of this
11:46:36 12 paragraph. And I'd like to ask -- and let me read it.

11:46:42 13 Quote,

11:46:42 14 "In addition if it is known that above a
11:46:45 15 certain dose or beyond a certain duration of use
11:46:49 16 toxicity is increased to an extent that the risk
11:46:52 17 exceeds the benefit, that dose or duration must be
11:46:55 18 identified."

11:46:56 19 Is this consistent with FDA's current
11:46:59 20 understanding?

11:47:00 21 A Yes, it is.

11:47:00 22 Q Can you explain what FDA means by this here.

11:47:06 23 A Some drugs, if you give them for a long period of time,
11:47:10 24 can be -- can be risky. Even if there is some little
11:47:15 25 continued benefit, if the risk outweighs the benefit, FDA

1 considers it necessary to include a limitation on the duration
2 of use in this section.

3 Q Now, if the treatment benefit FDA approved for Vascepa
4 had simply been to get TGs below 500 milligrams per deciliter
5 and not to maintain TGs below 500 milligrams per deciliter, in
6 your opinion, would there be a duration of use limitation in
7 the dosage and administration section of the Vascepa label?

8 A Yes, there would be.

9 Q And on the other hand, if the treatment benefit FDA
10 identified had been to reduce triglycerides and maintain that
11 reduction in triglycerides over the long term, would the
12 dosage and administration section of the Vascepa label have a
13 limit on duration?

14 A No, it would not.

15 Q And does the dosage and limitation section of the Vascepa
16 label in fact limit the duration of use for Vascepa?

17 A No, it goes not.

18 Q Now, in your opinion, based on the Vascepa labeling, did
19 FDA approve Vascepa label for long-term use including for 12
20 weeks or longer?

21 A Yes.

22 Q In your opinion, based on the labeling, did FDA determine
23 that Vascepa is safe and effective to reduce triglycerides in
24 adult patients with severe hypertriglyceridemia when
25 administered for 12 or more weeks?

11:48:36 1 A Yes.

11:48:37 2 MR. M. KENNEDY: So I would like to switch gears
11:48:39 3 to a few other issues here.

11:48:41 4 Mr. Brooks, can we have PX 1186.

11:48:41 5 BY MR. M. KENNEDY:

11:48:45 6 Q And, Dr. Peck, I assume you recognize document if you've
11:48:49 7 been in court, but what is it?

11:48:50 8 A This is the Vascepa label. And -- well, it's the Vascepa
11:48:58 9 label, the most recent one.

11:49:01 10 MR. M. KENNEDY: Mr. Brooks, can we turn to the
11:49:03 11 clinical studies section on page 11 and focus on Table 2 and
11:49:07 12 the material under Table 2.

11:49:10 13 And, in particular, Dr. Peck, I would like to
11:49:15 14 ask you about the data here concerning LDL-C.

11:49:19 15 In your opinion, based on the approved labeling,
11:49:22 16 did FDA determine that Vascepa was safe and effective to
11:49:26 17 reduce triglycerides in adult patients with severe
11:49:30 18 hypertriglyceridemia without raising LDL-C.

11:49:32 19 A Yes.

11:49:33 20 Q Is FDA's judgment in this regard reflected in the Vascepa
11:49:38 21 labeling?

11:49:38 22 A It is.

11:49:40 23 Q In which sections?

11:49:41 24 A Well, definitely in this section, the clinical studies'
11:49:47 25 section.

11:49:48 1 Q So what portions of the clinical study section speak to
11:49:54 2 Vascepa's effect on LDL-C?

11:49:56 3 A Well, first of all, in the table, and you've conveniently
11:50:01 4 highlighted this, in the left-hand column, the second row,
11:50:05 5 LDL-C, and if you go over to the far right column, you can see
11:50:10 6 that the median percent change relative to placebo was minus
11:50:19 7 two percent, meaning that there was -- there was on the median
11:50:27 8 no increase during the 12-week therapy with Vascepa.

11:50:32 9 Q Now, is it common to report median effects in drug
11:50:36 10 labeling?

11:50:37 11 A Would you repeat that?

11:50:38 12 Q I'm sorry. Is it common to report median effects in drug
11:50:44 13 labeling?

11:50:44 14 A It is.

11:50:45 15 Q Does that mean every that patient who takes Vascepa
11:50:48 16 according to the prescribing information will experience the
11:50:50 17 exact effects shown in Table 2?

11:50:53 18 A No.

11:50:53 19 Q Based on the data in the clinical studies section, what
11:50:58 20 percentage of patients can physicians expect to experience a
11:51:03 21 reduction in triglycerides without an increase in LDL-C?

11:51:07 22 A More than 50 percent.

11:51:08 23 Q I would like to ask you about the material underneath
11:51:11 24 Table 2 which says, quote,

11:51:13 25 "Vascepa 4 grams per day reduced median TG,

11:51:21 1 VLDL-C, and apo B levels from baseline relative to
11:51:27 2 placebo. The reduction in TG observed with Vascepa
11:51:30 3 was not associated with elevations in LDL-C relative
11:51:34 4 to placebo."

11:51:35 5 In your experience, what is FDA hoping to
11:51:38 6 achieve by putting this additional information below the table
11:51:41 7 in the clinical study section of a label?

11:51:44 8 A Well, I think it's calling out to the prescriber that
11:51:52 9 these particular observations on other lipids did not go up
11:52:01 10 during the treatment with Vascepa, and, in fact, the apo B
11:52:08 11 levels actually went down.

11:52:10 12 Q Does FDA intend prescribers to take into account the
11:52:14 13 verbiage below the table as well as the actual results?

11:52:17 14 A Yes.

11:52:18 15 Q Dr. Peck, are you familiar with the terms on-label and
11:52:21 16 off-label promotion?

11:52:23 17 A I am.

11:52:24 18 Q Is the term off-label promotion used by FDA in evaluating
11:52:30 19 drug promotion?

11:52:32 20 A Yes, it's a term of art, and it's a criterion against
11:52:36 21 which they regulate drug advertising.

11:52:40 22 Q What does off-label promotion mean in this context?

11:52:44 23 A Well, FDA requires that no statements be made in
11:52:50 24 advertisements that cannot be supported by verbiage or data in
11:52:55 25 the drug label.

11:52:56 1 So any deviation from statements in an advertisement
11:53:02 2 that are not supported by the data the representations in the
11:53:07 3 drug label are considered off-label and illegal.

11:53:11 4 Q And at a very high level in general, what happens if a
11:53:15 5 pharmaceutical company nonetheless engages in off-label
11:53:20 6 promotion?

11:53:20 7 A Well, FDA monitors such. It -- actually often companies
11:53:26 8 will approach FDA with a draft advertisement and ask for their
11:53:30 9 input.

11:53:31 10 So the safe way to do is to present this to FDA
11:53:37 11 before the advertisement is used. But if the unwise company
11:53:43 12 publishes an advertisement that goes beyond the information in
11:53:47 13 the label, FDA's authority permits it to -- to penalize the
11:53:59 14 manufacturer and require it to remove the drug advertisement
11:54:05 15 from -- from the public.

11:54:07 16 Q Can a drug manufacturer promote a drug for use only if
11:54:11 17 FDA has determined that it has shown to have been found to be
11:54:14 18 safe and effective based on the approved labeling?

11:54:17 19 A Yes.

11:54:18 20 Q Now, in evaluating whether a use has been found safe and
11:54:18 21 effective according to the labeling, can that evaluation
11:54:26 22 include the data in the clinical study section?

11:54:28 23 A Yes, it can.

11:54:29 24 Q Can a drug manufacturer use data in the clinical study
11:54:33 25 section of an FDA-approved drug label when promoting a drug?

11:54:38 1 A Would repeat that, please?

11:54:39 2 Q I'm sorry. Can a drug manufacturer -- strike that.

11:54:42 3 Can a drug manufacturer legally use data in the
11:54:46 4 clinical study section of an FDA-approved drug when promoting
11:54:50 5 that drug?

11:54:51 6 A Yes, it can, as long as it's emphasizing that the primary
11:54:57 7 indication is the one that's listed in the label.

11:55:00 8 Q Dr. Peck, do you know whether Amarin has, in fact,
11:55:03 9 promoted Vascepa by referencing that Vascepa can reduce
11:55:07 10 triglycerides without raising LDL-C?

11:55:10 11 A Yes, I am aware.

11:55:12 12 MR. M. KENNEDY: And, Mr. Brooks, if we could
11:55:14 13 pull up PX 287 which is a document already in evidence.

11:55:14 14 BY MR. M. KENNEDY:

11:55:21 15 Q Dr. Peck, do you recognize this document?

11:55:23 16 A Yes, I do.

11:55:24 17 Q What is it?

11:55:25 18 A This is an advertisement for Vascepa.

11:55:28 19 Q Is this a document you relied on in forming your opinions
11:55:31 20 in this case?

11:55:32 21 A Yes, it is.

11:55:33 22 Q Does this advertisement reference Vascepa's effects on
11:55:37 23 LDL-C?

11:55:38 24 A Yes, it does, in the context of reducing
11:55:44 25 hypertriglyceridemia.

11:55:46 1 MR. M. KENNEDY: Mr. Brooks, if we could blow up
11:55:47 2 on the top right.

11:55:47 3 BY MR. M. KENNEDY:

11:55:50 4 Q And I would like to focus on the second blurb here which
11:55:55 5 reads, quote,

11:55:57 6 "Vascepa, along with diet, is clinically
11:56:00 7 proven to lower very high triglycerides by 33 percent
11:56:04 8 in adults without raising bad cholesterol."

11:56:08 9 Do you see that?

11:56:08 10 A Yes.

11:56:09 11 Q Now, do you understand bad cholesterol to be a reference
11:56:12 12 to LDL-C?

11:56:13 13 A I do. And, in fact, there's a footnote that confirms
11:56:18 14 that.

11:56:19 15 Q Now, in your opinion, could Amarin legally promote
11:56:22 16 Vascepa based on its ability to reduce triglycerides without
11:56:26 17 raising LDL-C, if that were an off-label use?

11:56:30 18 A No, it could not.

11:56:31 19 Q In your opinion, could Amarin promote Vascepa based on
11:56:35 20 its ability to reduce TGs without raising LDL-C if the
11:56:40 21 approved labeling did not demonstrate that FDA had determined
11:56:45 22 that Vascepa was safe and effective for that use?

11:56:48 23 A No.

11:56:49 24 MR. M. KENNEDY: So, Mr. Brooks, let's go back
11:56:50 25 to PX 1186.

11:56:50 1 BY MR. M. KENNEDY:

11:56:54 2 Q And I would like to once again look at the Table 2 and
11:56:58 3 the material below it.

11:57:00 4 And, Dr. Peck, looking at the material below Table
11:57:05 5 2, what does this say about Vascepa's effects on TG, VLDL-C,
11:57:12 6 and apo B?

11:57:17 7 A Well, it basically states that when treating
11:57:22 8 hypertriglyceridemia, the physician can expect that TG,
11:57:29 9 VLDL-C, and apo B are likely to go down in many of his
11:57:34 10 patients.

11:57:35 11 Q Would the analysis we just walked through with respect to
11:57:38 12 LDL-C apply equally to Vascepa's effects on TG, VLDL-C, and
11:57:45 13 apo B?

11:57:45 14 A Yes.

11:57:46 15 Q Do these statements in the approved labeling establish
11:57:49 16 that FDA determined that Vascepa is safe and effective to
11:57:53 17 reduce triglycerides in adult patients with severe
11:57:58 18 hypertriglyceridemia while also lowering apo B?

11:58:01 19 A Yes.

11:58:01 20 Q So, Dr. Peck, do you recall when Dr. Sheinberg testified
11:58:06 21 that Vascepa's label is completely silent as to whether
11:58:10 22 Vascepa should be administered without concurrent lipid
11:58:14 23 altering therapy? Do you remember that testimony?

11:58:16 24 A Yes, I do.

11:58:17 25 Q Do you agree with Dr. Sheinberg?

11:58:19 1 A No, I do not.

11:58:20 2 Q First of all, for purposes of this line of questions, can
11:58:23 3 we use the term monotherapy to refer to the administration of
11:58:27 4 Vascepa as an adjunct to diet without concurrent
11:58:30 5 administration of any other lipid-altering medication?

11:58:35 6 A Yes, that would be an appropriate term or use of the word
11:58:39 7 monotherapy in this context.

11:58:40 8 Q In your opinion, did FDA determine that Vascepa is safe
11:58:44 9 and effective as a monotherapy to reduce triglycerides in
11:58:48 10 adult patients with severe hypertriglyceridemia?

11:58:53 11 A Yes.

11:58:54 12 Q In your opinion, is FDA's determination in this regard
11:58:56 13 reflected in the approved Vascepa labeling?

11:58:57 14 A Yes, it is.

11:58:58 15 Q Are there particular sections of the Vascepa labeling
11:59:01 16 reflect FDA's determination?

11:59:03 17 A There are at least three.

11:59:04 18 Q Which are?

11:59:05 19 A Those would be the indications and usage, dosage and
11:59:10 20 administration, and the clinical trial sections.

11:59:13 21 MR. M. KENNEDY: Can we go back to PX 572. And
11:59:16 22 this is the FDA guidance regarding the dosage and
11:59:20 23 administration section, and I would like to go to page 8 under
11:59:30 24 Concomitant Medication.

11:59:30 25

11:59:30 1 BY MR. M. KENNEDY:

11:59:33 2 Q And, Dr. Peck, in general, what is the purpose of this
11:59:36 3 portion of the FDA guidance on the dosage and administration
11:59:40 4 section of the labeling?

11:59:41 5 A It's to advise manufactures to include, or not,
11:59:46 6 information about any additional medication that should be
11:59:52 7 used in conjunction with the drug -- with the -- in this case,
11:59:57 8 Vascepa, in order to achieve adequate effectiveness or to
12:00:04 9 mitigate a safety issue.

12:00:07 10 Q I would like to ask you a couple questions about the
12:00:10 11 first sentence of this passage which reads, quote,

12:00:15 12 "This section should identify and describe
12:00:18 13 any recommended concomitant medications intended to
12:00:22 14 minimize toxicity, e.g., anti-emetics administered
12:00:28 15 with chemotherapy, or enhance effectiveness, e.g.,
12:00:33 16 heparin administered with antithrombotics or
12:00:36 17 thrombolytics in acute coronary syndrome," unquote.

12:00:41 18 Is what I just read consistent with, in your
12:00:41 19 view, FDA's current thinking on when the dosage and
12:00:44 20 administration section should identify concomitant
12:00:47 21 medications?

12:00:47 22 A Yes.

12:00:48 23 Q According to this passage, if FDA intends to recommend
12:00:52 24 that concomitant medication be used to minimize a drug's
12:00:52 25 toxicity or enhance its effectiveness, would that

12:00:52 1 recommendation have to appear in the dosage and administration
12:01:04 2 section?

12:01:04 3 A Yes.

12:01:05 4 Q Let me ask you a couple of questions about the second
12:01:07 5 sentence, and this reads as follows, quote,

12:01:11 6 "If the drug had been demonstrated to be
12:01:13 7 effective only in combination with another therapy,
12:01:16 8 e.g., an add-on epilepsy therapy, the section should
12:01:21 9 identify the therapy and cross-reference the
12:01:23 10 discussion of combination therapy in the indication
12:01:26 11 and usage section."

12:01:28 12 Is what I just read consistent with your
12:01:31 13 understanding of FDA's current thinking?

12:01:34 14 A Yes.

12:01:35 15 Q According to this guidance, if FDA has determined that a
12:01:37 16 drug is effective only in combination with another therapy,
12:01:40 17 would the dosage and administration section of the label have
12:01:43 18 to identify that therapy?

12:01:44 19 A Yes.

12:01:45 20 Q Based on your understanding of this guidance, if FDA had
12:01:49 21 determined that Vascepa was safe and effective only when used
12:01:53 22 with a concurrent lipid-altering medication, would the dosage
12:01:58 23 and administration section of Vascepa labeling identify that
12:02:00 24 therapy?

12:02:01 25 A Yes.

12:02:02 1 Q Does the dosage and administration section of the Vascepa
12:02:05 2 label include any recommendation -- strike that.

12:02:08 3 Does the dosage and administration section of the
12:02:12 4 Vascepa label include a limitation recommending administration
12:02:16 5 of a concurrent lipid-altering therapy?

12:02:19 6 A No, it does not.

12:02:20 7 Q In your opinion, did FDA approve Vascepa as a monotherapy
12:02:24 8 to reduce triglycerides in adult patients with severe
12:02:26 9 hypertriglyceridemia?

12:02:27 10 A Yes.

12:02:28 11 MR. M. KENNEDY: Dr. Peck, Thank you very much.
12:02:30 12 I have no further questions at this time.

12:02:35 13 Your Honor, it's about noon. May I suggest, if
12:02:37 14 it's okay with Your Honor, if we take our lunch at this point?

12:02:41 15 THE COURT: Well, Mr. Klein, would you prefer to
12:02:43 16 begin your cross-examination now?

12:02:45 17 MR. KLEIN: I'm fine with taking a lunch break.

12:02:48 18 THE COURT: How long do you think your
12:02:50 19 cross-examination will be?

12:02:52 20 MR. KLEIN: Roughly an hour, maybe less.

12:02:57 21 THE COURT: If you had said 30 minutes, I would
12:02:58 22 say let's resume, let's continue, but, is there a particular
12:03:03 23 reason why, Mr. Kennedy, you suggest lunch now?

12:03:06 24 MR. M. KENNEDY: Just that it's noon.

12:03:10 25 MR. KLEIN: I could start --

12:03:11 1 MR. M. KENNEDY: I didn't eat breakfast today.

12:03:14 2 THE COURT: I think that's a good reason to take

12:03:16 3 a lunch break. All right. We'll take our lunch break.

12:03:20 4 MR. M. KENNEDY: Thank you very much, Your
5 Honor.

6 (The noon recess was taken.)

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4 THE COURT: Please be seated.

5 Mr. Klein, are you ready to proceed?

6 MR. KLEIN: I am. Thank you, Your Honor.

7 Good afternoon, Dr. Peck.

8 THE WITNESS: Good afternoon, Mr. Klein.

9 MR. KLEIN: We obviously met at your deposition,
10 but, for the record, I'm Charles Klein. I'll ask you a few
11 questions on behalf of the defendants.

12 CROSS-EXAMINATION

13 BY MR. KLEIN:

14 Q I want to start off by making sure you understand what is
15 and is not disputed in this case. Do you understand that
16 there is no dispute that the scope of the Vascepa label
17 includes long-term use of the drug?

18 A If you say so.

19 Q Okay. Do you understand -- and I'm asking these
20 questions based on some of the testimony you gave during your
21 direct, so I just want to make sure you understand what is
22 disputed and what is not.

23 Do you understand that there's no dispute that the
24 Vascepa label includes situations where Vascepa reduces
25 triglycerides below 500 and the patient needs to continue to

12:38:46 1 take Vascepa to maintain levels below 500?

12:38:50 2 A Yes.

12:38:51 3 Q And do you understand that Dr. Sheinberg agreed that the
12:38:54 4 label includes those types of situations?

12:38:57 5 A Well, he seemed to argue it both ways, actually.

12:39:02 6 Q Okay. Well, you understand that there's no dispute that
12:39:06 7 some patients have genetic issues that cause triglycerides way
12:39:13 8 above 500 regardless of whether the patient is on an
12:39:17 9 appropriate diet and exercises, right?

12:39:19 10 A Yes, I understand that.

12:39:21 11 Q Okay. And those patients have a chronic condition?

12:39:23 12 A Yes.

12:39:24 13 Q Okay. And there's no dispute that the label includes
12:39:27 14 those types of patients. Do you understand that?

12:39:29 15 A Yes.

12:39:29 16 Q And -- but there's a large number of patients who have
12:39:33 17 triglycerides above 500 due to lifestyle choices. Do you
12:39:39 18 understand that?

12:39:39 19 A I don't have any actual personal knowledge about that.
12:39:44 20 That's an epidemiological matter. I haven't studied that.

12:39:47 21 Q Okay. But you heard testimony along those lines during
12:39:51 22 the trial?

12:39:51 23 A I heard varied testimony on that issue, yes.

12:39:54 24 Q Okay. And you heard testimony that there are patients
12:39:58 25 who can take a short-term course of Vascepa to drop their

12:40:04 1 triglycerides below 500, but maintain levels below 500 with
12:40:10 2 diet and exercise alone, right?

12:40:13 3 A I did hear that, yes.

12:40:13 4 Q And the label includes those types of patients as well,
12:40:17 5 right?

12:40:17 6 A There is a small fraction of patients in the placebo
12:40:22 7 group who achieved that on -- you know, without Vascepa.

12:40:28 8 Q Okay. And I'll get back to that.

12:40:31 9 And you heard testimony that sometimes severe
12:40:36 10 hypertriglyceridemia has acute causes?

12:40:38 11 A Yes.

12:40:38 12 Q Okay. And do you understand that a core issue in this
12:40:44 13 case is whether the Vascepa labelling requires elimination of
12:40:47 14 these acute causes before initiating Vascepa?

12:40:50 15 A Yes.

12:40:51 16 Q And do you understand that Amarin's position in this case
12:40:55 17 is that the indicated use of Vascepa is limited to chronic
12:41:00 18 use, that is, the patients who have a chronic condition
12:41:03 19 requiring long-term therapy?

12:41:06 20 A I understand their position to be that the label
12:41:10 21 encourages the -- the use in this condition.

12:41:16 22 Q Okay. And so you don't understand that Amarin's position
12:41:21 23 is that the indicated use of Vascepa is limited to chronic
12:41:24 24 use? Is that an understanding you have?

12:41:26 25 A So, I wasn't here for the opening statement, and so

12:41:30 1 you'll have to represent to me what you think Amarin's
12:41:33 2 position is.

12:41:33 3 Q Okay. No. I mean, Amarin is perfectly able to represent
12:41:38 4 its own positions. I just wanted to understand what your
12:41:43 5 understanding was.

12:41:45 6 MR. KLEIN: Mr. Gross, can we go to DDX 1.15.

12:41:45 7 BY MR. KLEIN:

12:41:51 8 Q Now, Dr. Peck, you just said you weren't here for opening
12:41:54 9 statements, right?

12:41:55 10 A Repeat that, please?

12:41:56 11 Q You were not here for opening statements?

12:41:58 12 A No, I was not.

12:41:59 13 Q Were you here for Dr. Budoff's testimony?

12:42:01 14 A Yes, I was, yes.

12:42:02 15 Q Okay. And you were obviously here for Dr. Sheinberg's
12:42:05 16 testimony.

12:42:05 17 A Yes, I was, yeah.

12:42:07 18 Q So and you saw this slide before, DDX 1.15?

12:42:10 19 A Yes, I did.

12:42:11 20 Q Okay. And this slide relates a Q and A from the
12:42:17 21 deposition where I asked you, "And is the indicated use of
12:42:20 22 Vascepa limited to chronic use," and you said, "No, I don't
12:42:23 23 think so."

12:42:24 24 That's what you've said at the deposition, right?

12:42:27 25 A Right. That's what I said. And you asked about a

12:42:29 1 limitation. There is no limitation with respect to chronic
12:42:35 2 use.

12:42:39 3 Q Okay. Just -- well, you understand -- you were here when
12:42:43 4 Dr. Sheinberg agreed with your deposition testimony, right?

12:42:45 5 A Yes.

12:42:45 6 Q And you're not changing your testimony today, right?

12:42:48 7 A No.

12:42:51 8 Q Okay. So just to be clear, the MARINE indication in the
12:42:55 9 Vascepa label, and the indicated use of icosapent in
12:43:00 10 defendants' labels, is not limited to chronic use, correct?

12:43:03 11 A Yes.

12:43:08 12 MR. KLEIN: Mr. Gross, can we go to DDX 7.2.

12:43:08 13 BY MR. KLEIN:

12:43:19 14 Q And, Dr. Peck, you've seen the new Vascepa label; is that
12:43:22 15 correct?

12:43:23 16 A Repeat that, please?

12:43:25 17 Q Have you seen the new Vascepa label?

12:43:27 18 A Oh, yes. Yes, of course.

12:43:29 19 Q Okay. I just want to ask you a few questions to clarify
12:43:33 20 what has changed between the two labels, okay, just so
12:43:37 21 everyone is on the same page.

12:43:39 22 Now, on the screen, DDX 7.2, is DX 1698, page 2. Do
12:43:46 23 you recognize that as the 2017 Vascepa indication?

12:43:50 24 A Yes.

12:43:52 25 Q Okay.

12:43:52 1 A Well, it's -- it's -- yes, that's the indication.

12:43:56 2 Q Okay. There are parts in the indication -- like there
12:43:59 3 were limitations of use.

12:44:00 4 A Right.

12:44:00 5 Q But that's not in this slide.

12:44:02 6 A Right.

12:44:02 7 Q Is that why you hesitated?

12:44:04 8 A Yes, it is.

12:44:05 9 Q Okay. Then on the bottom is DX 2248, page 2, and do you
12:44:10 10 recognize that as the current MARINE indication for Vascepa?

12:44:16 11 A Yes.

12:44:16 12 Q All right. Now, the old MARINE indication -- actually
12:44:23 13 the only old indication, had a usage considerations section,
12:44:28 14 right?

12:44:33 15 A I think so, yes.

12:44:34 16 Q Yeah. And it said,

12:44:37 17 "Patients should be placed on an appropriate
12:44:39 18 lipid lowering diet and exercise regimen before
12:44:43 19 receiving Vascepa, and should continue this diet and
12:44:46 20 exercise regimen with Vascepa."

12:44:48 21 Do you see that on the screen?

12:44:49 22 A Yes, I do. Yes.

12:44:50 23 Q Okay. And you understand that that usage consideration
12:44:54 24 statement has been removed from the current Vascepa
12:44:58 25 indication.

12:45:00 1 A Yes.

12:45:01 2 Q Okay. And so, as a result, you understand that
12:45:04 3 defendants' labeling, their current labels, do not include
12:45:08 4 this usage consideration statement from the 2017 Vascepa
12:45:14 5 label?

12:45:14 6 A Yes.

12:45:15 7 Q And -- but just to be clear, when you gave the testimony
12:45:23 8 that the indicated use is not limited to chronic use, that
12:45:31 9 testimony related to the 2017 indication that included this
12:45:35 10 usage consideration language, correct?

12:45:38 11 A No, it applies to the 2019 as well.

12:45:41 12 Q No, I understand. When you gave the testimony that was
12:45:44 13 on the screen that the indicated use is not limited to chronic
12:45:52 14 use, at the time the indication you were referring to was the
12:45:55 15 2017 Vascepa indication that had this usage considerations
12:46:00 16 language, right?

12:46:01 17 A Yes.

12:46:02 18 Q Yeah. Because the new Vascepa label just came out a few
12:46:07 19 weeks ago.

12:46:08 20 A That's correct.

12:46:10 21 MR. KLEIN: Right.

12:46:12 22 Let's go to DDX 7.3. Okay. Here, I am
12:46:22 23 comparing the two labels, the February 2017 Vascepa label to
12:46:27 24 the new Vascepa label, and, again, it's DX 1689 -- 1698 and
12:46:40 25 2248.

12:46:40 1 BY MR. KLEIN:

12:46:41 2 Q And there's a sentence that appears in both labels that
12:46:45 3 says,

12:46:45 4 "Patients should engage in appropriate
12:46:48 5 nutritional intake and physical activity before
12:46:51 6 receiving Vascepa which should continue during
12:46:55 7 treatment with Vascepa."

12:46:57 8 Do you see that?

12:46:57 9 A Yes, I do.

12:46:58 10 Q Okay. So that phrase has not changed in the old and new
12:47:01 11 label, right?

12:47:02 12 A Uh-huh, yes.

12:47:03 13 Q Okay. So to be clear, FDA did not move the usage
12:47:11 14 considerations statement from the old indication into the
12:47:14 15 dosage and administration section, it just eliminated that
12:47:20 16 statement, correct?

12:47:20 17 A That's correct.

12:47:26 18 MR. KLEIN: Can we go to DDX 7.1, please.

12:47:26 19 BY MR. KLEIN:

12:47:30 20 Q Okay. I want to focus on the indication, and I think you
12:47:34 21 said this on direct, but the MARINE indication in the current
12:47:41 22 Vascepa label is materially identical to the indications in
12:47:45 23 Hikma's and DRL's respective proposed labels, correct?

12:47:51 24 A Yes.

12:47:51 25 Q Okay. And, in general,

12:47:52 1 "The indications and usage section must list
12:47:56 2 important aspects of the approved indication such as
12:47:58 3 whether the drug is approved for selected patient
12:48:02 4 subgroups," correct?

12:48:03 5 A Repeat that, please?

12:48:07 6 Q Sure.

12:48:08 7 "The indications and usage section must list
12:48:11 8 important aspects of the approved indication such as
12:48:15 9 whether the drug is approved for selected patient
12:48:18 10 subgroups," correct?

12:48:19 11 A And you're reading from what?

12:48:21 12 Q I'm actually reading from your reply report, and I can
12:48:25 13 put it up if that's helpful.

12:48:27 14 A So what was my reply a reply to?

12:48:32 15 Q No, your expert report.

12:48:34 16 A I understand that. But you just expressed a phrase that
12:48:40 17 you ascribed to me in my report, and I would like to know what
12:48:45 18 section that was in so I can get the context.

12:48:48 19 MR. KLEIN: Sure. Can we put up DDX 7.4.

12:48:48 20 BY MR. KLEIN:

12:48:55 21 Q All right. This is paragraph 129 from your reply report,
12:48:58 22 and here you're describing the indications and usage section,
12:49:02 23 and I'll read it. You say,

12:49:03 24 "To this end, the indications and usage
12:49:06 25 section concisely comprises the indication, and, as

12:49:10 1 appropriate, any identified limitations of use. This
12:49:14 2 section must identify the disease, condition, or
12:49:17 3 symptom for which the drug is approved, and list
12:49:20 4 other important aspects of the approved indication
12:49:23 5 such as whether the drug is approved for selected
12:49:26 6 patient subgroups."

12:49:28 7 So all -- this is general statement. Is that an
12:49:31 8 accurate statement with regard to the indications and usage?

12:49:34 9 A Yes. Yes, I believe it is.

12:49:36 10 Q And the only limitations in the MARINE indication refer
12:49:44 11 to age, referring to an adult patient, and medical condition,
12:49:48 12 referring to severe hypertriglyceridemia, correct?

12:49:51 13 A Sir, I'm not sure what you mean by MARINE indication. I
12:49:56 14 mean, the indication is in the label. MARINE was a clinical
12:50:00 15 study that had end points and particular conditions.

12:50:02 16 But what do you mean by the MARINE indication?

12:50:05 17 Q Okay. So, Dr. Peck, we've been using this litigation
12:50:09 18 shorthand MARINE indication for the Vascepa -- now that there
12:50:12 19 are two Vascepa indications, we've been calling the original
12:50:16 20 Vascepa indication the MARINE indication.

12:50:19 21 I totally understand your comment which is that, you
12:50:22 22 know, the label doesn't even mention MARINE. It's really
12:50:26 23 shorthand for this litigation, but I can rephrase.

12:50:30 24 The only limitation in the indication for severe
12:50:34 25 hypertriglyceridemia, the only limitations refer to age, the

12:50:41 1 patient has to be an adult, and medical condition, the patient
12:50:45 2 has to have severe hypertriglyceridemia, correct?

12:50:47 3 A Yes, I can agree to that. Yes.

12:50:50 4 Q Okay. And the FDA-approved indication -- I'm sorry, the
12:50:55 5 FDA-approved labeling for the severe hypertriglyceridemia
12:50:59 6 indication does not limit a patient population for whom
12:51:05 7 Vascepa is approved based on a prior diet, correct?

12:51:10 8 A Based on what?

12:51:11 9 Q A prior diet.

12:51:13 10 A I'm not sure I understand your question.

12:51:23 11 MR. KLEIN: Okay. Can we go to DDX 7.6.

12:51:23 12 BY MR. KLEIN:

12:51:29 13 Q So we're looking now at PX 183, which is your reply
12:51:33 14 expert report, paragraph 241.

12:51:36 15 And in this paragraph you said,

12:51:38 16 "The FDA-approved labeling does not limit the
12:51:42 17 patient population for whom Vascepa is approved based
12:51:45 18 on prior diet."

12:51:47 19 Do you see that?

12:51:47 20 A I do. Yeah.

12:51:49 21 Q And that's a true fact?

12:51:49 22 A So now I see the context, yes.

12:51:53 23 Q Okay. And if FDA intended to limit the indication for
12:52:01 24 severe hypertriglyceridemia to patients who previously tried a
12:52:06 25 diet, FDA would have so stated in the indications and usage

12:52:11 1 section, correct?

12:52:13 2 A I think if FDA considered that to be a crucial condition
12:52:22 3 which deserved attention and encouragement in the indications
12:52:29 4 and usage section -- FDA uses its best judgment. FDA
12:52:34 5 reviewers are -- many of them are physicians, they understand
12:52:39 6 clinical situations and the challenge of writing
12:52:43 7 prescriptions. So I don't think I can entirely agree with
12:52:46 8 what you just said.

12:52:47 9 Q Okay. Let's go to DDX 7.7, which is this same paragraph,
12:52:53 10 paragraph 241, and I'm just highlighting a different sentence.

12:52:57 11 And here, in this same paragraph, you said,

12:53:00 12 "If FDA had intended to limit Vascepa's
12:53:04 13 approval to patients who previously consumed a
12:53:07 14 particular diet, it would have so stated in the
12:53:10 15 indications and usage section," and then you cited
12:53:13 16 FDA guidance.

12:53:14 17 Do you see that?

12:53:15 18 A Yes.

12:53:15 19 Q Okay. So is that an accurate statement, that if FDA had
12:53:19 20 intended to limit Vascepa's approval to patients who
12:53:25 21 previously consumed a particular diet, it would have so stated
12:53:28 22 in the indications and usage section?

12:53:30 23 A Well, there's -- see, what FDA additionally said is
12:53:34 24 additional or qualifiers that are critical.

12:53:37 25 So that's a judgment matter by FDA reviewers with

12:53:41 1 respect to the criticality of a particular additional
12:53:47 2 descriptor.

12:53:48 3 Q Okay. And we'll take a look at the guidance in a moment
12:53:51 4 but I want to focus on your words first.

12:53:52 5 You said in your expert report,
12:53:54 6 "If FDA had intended to limit Vascepa's
12:53:57 7 approval to patients who previously consumed a
12:54:00 8 particular diet, it would have so stated in the
12:54:03 9 indications and usage section."

12:54:05 10 Are you standing by that statement that you
12:54:08 11 wrote in your report?

12:54:10 12 A Yes, as referenced in FDA's guidance.

12:54:14 13 Q Okay. Let's take a look at the guidance, DDX 7.8, and I
12:54:27 14 believe -- this is PX 573, and I believe this is now in
12:54:32 15 evidence, right? I believe this is one of the documents you
12:54:35 16 used?

12:54:35 17 A Yes, we discussed that earlier.

12:54:37 18 Q Okay. All right. So in this snapshot, what I did is I
12:54:44 19 tried to take what was in your footnote, okay, and this is
12:54:48 20 under the heading Indication, you see that?

12:54:50 21 A Yes.

12:54:50 22 Q Then there's a sub-bullet 2, "Other Information Necessary
12:54:56 23 to Describe Approved Indication," right?

12:54:59 24 A Yes.

12:54:59 25 Q And then it says -- there's sub-bullet A, "Selected

12:55:03 1 Patient Subgroups Or Disease Subpopulations For Whom the Drug
12:55:08 2 is Approved." Do you see that?

12:55:09 3 A Yes.

12:55:10 4 Q Okay. And then the guidelines say,

12:55:12 5 "In some cases additional descriptors or
12:55:17 6 qualifiers are critical to include as part of the
12:55:20 7 indication to clearly identify the patient population
12:55:23 8 for whom the drug is approved."

12:55:25 9 Do you see that?

12:55:26 10 A Yes, I do.

12:55:27 11 Q And so if there are select patient subgroups or disease
12:55:31 12 subpopulations, the indications should include additional
12:55:37 13 descriptions, descriptors or qualifiers that are critical to
12:55:40 14 clearly identify the patient population for whom the drug is
12:55:43 15 approved, right?

12:55:44 16 A Yes, that's what it says.

12:55:45 17 Q And just for the record, this is page 11, it's not on the
12:55:53 18 slide, of PX 573.

12:55:56 19 And those additional descriptors or qualifiers would
12:56:03 20 be required if, for example, as the guidance says, "The
12:56:09 21 indication" -- wait. Where am I?

12:56:21 22 "The indication is limited to using a drug
12:56:24 23 for patients previously treated with other
12:56:28 24 therapies."

12:56:29 25 It's at the end of the highlight. Do you see

12:56:31 1 that?

12:56:31 2 A Yes, I do.

12:56:33 3 MR. KLEIN: Okay. All right.

12:56:34 4 THE COURT: Mr. Klein, you indicated this was
12:56:36 5 from -- I can pull up the document, too. You indicated this
12:56:40 6 is from page 11, but on top it says P08. So is it on 11 or 8?

12:56:53 7 MR. KLEIN: It's page 8 of the guidance, but
12:56:56 8 it's page 11 in the PX page number.

12:57:01 9 THE COURT: Okay. Thank you.

12:57:04 10 MR. KLEIN: And just to be clear, the indication
12:57:06 11 at the top is from an earlier page, but that's indicated by
12:57:10 12 the break.

12:57:10 13 BY MR. KLEIN:

12:57:13 14 Q All right. So just to circle back to where we were a
12:57:17 15 moment ago,

12:57:18 16 "The additional descriptors or qualifiers
12:57:21 17 would be required in the indication if, for example,
12:57:24 18 the indication is to be limited to using a drug for
12:57:28 19 patients who were previously treated with other
12:57:32 20 therapies," right?

12:57:32 21 A Yes.

12:57:33 22 Q Okay. And,

12:57:34 23 "The absence of any limitation in defendants'
12:57:39 24 labels and the Vascepa label concerning a particular
12:57:43 25 diet in defendants" --

12:57:47 1 Strike that. Let me start again.

12:57:48 2 "The absence of any limitation concerning a
12:57:52 3 particular diet in defendants' indication conveys to
12:57:54 4 physicians that the approved patient population is
12:57:57 5 bounded by only two characteristics, age and disease
12:58:01 6 condition," correct?

12:58:06 7 A Well, in the -- I mean --

12:58:11 8 Q In defendants' labels.

12:58:13 9 A Pull up the label so we can examine it, just your
12:58:18 10 assertion.

12:58:19 11 MR. KLEIN: Let's go back to DDX 7.1. Okay.
12:58:24 12 I'll repeat the question.

12:58:24 13 BY MR. KLEIN:

12:58:25 14 Q "The absence of any limitation concerning a
12:58:28 15 particular diet in defendants' indication conveys to
12:58:32 16 physicians that the approved patient population is
12:58:36 17 bounded by only two characteristics, age and disease
12:58:39 18 condition," correct?

12:58:42 19 A Well, the phrase adjunct to diet is an indicator of what
12:58:49 20 FDA intends to encourage the prescriber to employ.

12:58:56 21 Q Okay.

12:58:57 22 A So I think you're sort of overlooking that.

12:59:01 23 Q Let's go to DDX 7.9. This is the same paragraph we've
12:59:08 24 been looking at from your expert report, paragraph 241 from
12:59:13 25 PX 183, and I'll read the last two sentences from this

1 paragraph.

2 "If FDA had intended to limit Vascepa's
3 approval to patients who previously consumed a
4 particular diet, it would have so stated in the
5 indications and usage section. The absence of any
6 such limitation thus conveys to physicians that the
7 approved patient population is bounded by only two
8 characteristics, age and disease condition."

9 Do you stand by those statements in your expert
10 report?

11 A Well, yeah. I think that's a true statement.

12 Q Okay. And defendants' proposed indication -- I'm
13 focusing on the indication for now, I'll get to other sections
14 in a bit. But defendants' proposed indication does not
15 encourage doctors to use icosapent for any particular
16 duration, correct?

17 A Well, I think it encourages a physician to use it
18 indefinitely, as long as necessary.

19 Q But it doesn't -- there's no statement in the indication
20 with regard to duration of therapy in the indication, correct?

21 A Well, as you know, by regulation and by guidance, it
22 shouldn't be there if FDA considered this to be a chronic
23 condition --

24 Q Okay. Defendants --

25 A -- that requires long-term therapy. So its absence is

01:00:43 1 deliberate.

01:00:44 2 Q So,

01:00:53 3 "The concise indication in defendants' labels
01:00:56 4 does not include any limitation, and the usage does
01:01:00 5 not include any limitation with respect to duration
01:01:03 6 of therapy," correct?

01:01:04 7 A Are you reading from a document?

01:01:07 8 Q I'm reading from your deposition.

01:01:09 9 A Okay. What question was I answering in that deposition?

01:01:15 10 Q Okay. The question -- and I can play it if you would
01:01:18 11 like, but the question I asked during the deposition, this is
01:01:22 12 139 -- page 139, 21, to page 140, line 2,

01:01:27 13 "And so the Vascepa indication is silent as
01:01:30 14 to duration of treatment, correct?"

01:01:33 15 There was an objection to form, and you
01:01:35 16 answered, "The concise indication does not include
01:01:38 17 any limitation, and the usage does not include any
01:01:42 18 limitation with respect to duration of therapy. "

01:01:45 19 Do you stand by that testimony?

01:01:46 20 A Yes, I do. Yes.

01:01:48 21 Q Okay. Now, let's go to DDX 7.1. Again, these -- this is
01:01:59 22 the indication we've been talking about, right?

01:02:03 23 A Yes.

01:02:04 24 Q And as you pointed out a moment ago, you said the
01:02:07 25 indication is for use as an adjunct to diet, right?

01:02:11 1 A Yes.

01:02:11 2 Q Okay. And in your view,

01:02:13 3 "The term adjunct in this context means that
01:02:16 4 doctors should use their best efforts to convince
01:02:20 5 patients to engage in appropriate diet and exercise,"
01:02:23 6 correct?

01:02:24 7 A I agree with that. I assume you're quoting something
01:02:26 8 again.

01:02:27 9 Q Yes.

01:02:27 10 A Sounds like me.

01:02:29 11 Q Okay. But to be clear, defendants' indication doesn't
01:02:33 12 preclude icosapent from being used in a patient who is unable
01:02:37 13 or unwilling to engage in appropriate diet and exercise.

01:02:41 14 Do you agree with that?

01:02:42 15 A I agree with that.

01:02:43 16 Q And when defendants' indication says Vascepa is indicated
01:02:50 17 as an adjunct to diet, this recommends that Vascepa and diet
01:02:55 18 be used in tandem, right?

01:02:58 19 A Optimally, yes.

01:02:59 20 Q But the indication does not suggest that Vascepa should
01:03:02 21 be withheld until a patient has successfully effected a change
01:03:08 22 in diet, correct?

01:03:09 23 A No, it does not say that specifically. I think many
01:03:14 24 practitioners would actually employ that procedure.

01:03:20 25 Q Let me -- let's go to DDX 7.10 to make sure you and I are

on the same page.

So here's another paragraph from your expert report, PX 183, and in the first two sentences you said,

"The labeling allows physicians to exercise their discretion as to both the timing and content of any diet counseling. To start, the labeling provides physicians with discretion as to timing. Vascepa is indicated as an adjunct to diet which recommends that Vascepa and diet be used in tandem, but does not suggest that Vascepa should be withheld until a patient has successfully effected a change in diet."

Do you stand by those two sentences in your report?

A Yes. Yes, I do.

Q All right. Let's go DDX 7.11. I now want to focus on the dosage and administration section.

And just for the record, this is the dosage and administration section from Hikma's label, DX 2256, but understand that this section is materially identical in Dr. Reddy's label as well?

A Yes.

Q Okay. And like the indications and usage section, the dosage and administration section does not specify any duration of treatment, correct?

A Well, there is no specific statement in there. But as

01:05:09 1 I -- as I developed in my direct, there is no reason to limit.
01:05:20 2 FDA intends there to be no limitation listed here.

01:05:24 3 Q Okay. Yeah. And I'm not asking about the guidance or
01:05:28 4 the regulations. It's just clear that when you look at the
01:05:33 5 dosage and administration section of defendants' labels, it
01:05:36 6 doesn't specify any specific duration of treatment, correct?

01:05:40 7 A That's correct.

01:05:41 8 Q And, in fact, neither the indication nor the dosage and
01:05:49 9 administration sections of defendants' labels in any way
01:05:53 10 limits the duration of treatment, correct?

01:05:57 11 A No -- I mean, yes, that's correct.

01:06:00 12 Q Okay. All right. The only statement as to timing in the
01:06:04 13 dosage and administration section is the second bullet under
01:06:09 14 2.1, which says,

01:06:10 15 "Patient should engage in appropriate
01:06:13 16 nutritional intake and physical activity before
01:06:16 17 receiving icosapent ethyl which should continue
01:06:21 18 during treatment with icosapent ethyl," correct?

01:06:23 19 A Yes.

01:06:23 20 Q And let's focus on the term should, where it says
01:06:27 21 "patient should engage." The term "should" implies a
01:06:30 22 recommendation to the doctor, but it doesn't limit the doctor
01:06:34 23 to a particular action, correct?

01:06:36 24 A Yes.

01:06:39 25 Q And so when FDA uses the term "should" in the dosage and

01:06:44 1 administration section, this is simply a suggestion leaving
01:06:48 2 actions to the wide discretion of the physician, correct?

01:06:51 3 A I think it's stronger than that. I think it's
01:06:55 4 affirmative. I think it's encouraging.

01:06:59 5 Q All right. Let me ask the question again to make sure
01:07:04 6 you understand the question.

01:07:05 7 When FDA uses the term "should" in a pharmaceutical
01:07:09 8 label, it is leaving certain actions to the wide discretion of
01:07:14 9 the physician; is that correct?

01:07:16 10 A The physician always has the discretion with respect to
01:07:19 11 any element of the label to use it as he sees fit in the best
01:07:25 12 interest of the patient.

01:07:27 13 Nonetheless, the label encourages many good
01:07:31 14 practices, and so when I see the word "should" in an FDA
01:07:38 15 label, I think that's a pretty strong encouragement.

01:07:41 16 MR. KLEIN: Okay. Mr. Gross, can you play
01:07:45 17 page 99 of the deposition, lines 2 through 9.

01:07:48 18 (Deposition video recording played.)

01:08:41 19 BY MR. KLEIN:

01:08:42 20 Q And so was it your testimony that when FDA uses the term
01:08:50 21 "should" in a pharmaceutical label, it is leaving certain
01:08:53 22 actions to the wide discretion of the physician?

01:08:56 23 A I think that's consistent with what I just said.

01:09:01 24 Q Okay. And that's what you said in the deposition.

01:09:03 25 A That's what I said. And, you know, a physician would

01:09:05 1 understand reading this that that's an encouragement.

01:09:08 2 Q Okay. But you -- again, you're not disputing your
01:09:13 3 deposition testimony --

01:09:14 4 A No, I'm not.

01:09:15 5 Q Okay. And the term appropriate -- so appropriate
01:09:20 6 nutritional intake, do you see that?

01:09:22 7 A Yes, I do.

01:09:23 8 Q Is actually a signal to the physician that it is up to
01:09:26 9 his or her discretion as to what is appropriate, correct?

01:09:30 10 A Yes. But, of course, physicians are trained in diets,
01:09:38 11 and given this condition, this would have a deeper meaning
01:09:44 12 "appropriate."

01:09:45 13 Q Well, right. But the label isn't telling doctors what
01:09:49 14 FDA thinks is appropriate. The label is leaving the
01:09:53 15 nutritional intake and physical activity for a particular
01:09:57 16 patient up to the discretion of the doctor, correct?

01:10:00 17 A I think so. I would have to reread the label to be sure
01:10:03 18 that the clinical study section doesn't have some additional
01:10:08 19 information about the type of diet that the patients were,
01:10:11 20 were -- I think lipid-lowering, you know, is listed in the
01:10:18 21 clinical study section.

01:10:20 22 So reading the label as a whole, I think there's a
01:10:23 23 little bit more information about what means appropriate.

01:10:28 24 Q Okay. And to be clear, the statement,

01:10:40 25 "Patients should engage if appropriate

01:10:41 1 nutritional intake and physical activity before
01:10:45 2 receiving icosapent,"
01:10:48 3 does not state how long diet and exercise should precede the
01:10:53 4 prescription, correct?

01:10:55 5 A No, it doesn't. It leaves that up to the physician's
01:10:59 6 education and experience and knowledge.

01:11:02 7 Q Exactly. So this statement that,
01:11:06 8 "Patients should engage in appropriate
01:11:09 9 nutritional intake and physical activity before
01:11:11 10 receiving icosapent ethyl,"
01:11:12 11 is not a requirement, it leaves the doctor with wide
01:11:16 12 discretion as to timing. Do you agree with that?

01:11:20 13 A Well, yes. And, as I said before, the physician always
01:11:24 14 has the discretion to use the drug in any way that he thinks
01:11:29 15 is in the best interest of the patient.

01:11:32 16 Q Right. And the point of this second bullet in
01:11:35 17 section 2.1 is really to emphasize that Vascepa is not
01:11:39 18 supposed to replace an appropriate diet and exercise regimen,
01:11:43 19 correct?

01:11:44 20 A I think that's overreach.

01:11:46 21 Q You think that's an overreach?

01:11:49 22 A Overreach, yeah, I wouldn't interpret it that way.

01:11:52 23 Q Okay. Well, the dosage and administration section does
01:11:55 24 not prevent physicians from, consistent with established
01:11:59 25 clinical practice, discussing diet changes and prescribing

01:12:03 1 Vascepa in the same visit. Do you agree with that?

01:12:06 2 A I agree with that.

01:12:10 3 Q Let's go DDX 7.14.

01:12:16 4 Okay. I'll explain this demonstrative so it's in
01:12:21 5 the record. We're looking at Hikma's proposed label,
01:12:25 6 section 2, and in particular section 2.1, and in the second
01:12:29 7 bullet I added a phrase, "and fail to maintain TGs below
01:12:35 8 500 milligrams per deciliter" after the phrase "patients
01:12:41 9 should engage in appropriate nutritional intake and physical
01:12:46 10 activity."

01:12:46 11 Do you see that?

01:12:47 12 A I do.

01:12:48 13 Q Okay. To be clear, the dosage and administration section
01:12:52 14 of defendants' labels does not require doctors to wait and see
01:12:56 15 if patients fail to maintain triglycerides below
01:13:01 16 500 milligrams per deciliter with diet and exercise before
01:13:04 17 prescribing icosapent. Do you agree with that?

01:13:08 18 A I agree with that.

01:13:09 19 Q And if FDA had determined that safety or efficacy
01:13:15 20 concerns required pretreatment diet changes or stabilization
01:13:18 21 prior to icosapent administration for a particular period of
01:13:22 22 time, it would have so stated in the labeling, correct?

01:13:27 23 A Well, it didn't. Are you telling me that Hikma's label
01:13:32 24 is going to modify the indication?

01:13:34 25 Q No, I'm not saying that. I'm just asking you -- well,

01:13:42 1 let's just leave the testimony as it is. But I will represent
01:13:45 2 to you that this is not a proposed modification of the label.

01:13:48 3 A Okay. That would certainly take it out of the generic
01:13:53 4 drug domain and put it into the 505(b)(2) or another
01:13:58 5 regulatory pathway.

01:13:59 6 Q Right. Let me ask the last question again because I
01:14:02 7 think we got distracted.

01:14:03 8 If FDA had determined that safety or efficacy
01:14:08 9 concerns required pretreatment diet changes or stabilization
01:14:12 10 prior to icosapent administration for a particular period of
01:14:15 11 time, it would have so stated in the labeling, correct?

01:14:19 12 A If the clinical trials had been structured in such a way
01:14:26 13 as to demonstrate that failure, or not failure, reached a
01:14:33 14 statistical difference, then FDA may -- would have been moved,
01:14:39 15 I assume, to engage with the sponsor with respect to a
01:14:43 16 modification of the label in this respect.

01:14:46 17 But I'm not sure why this -- what this hypothetical
01:14:49 18 has to do with our topic.

01:14:52 19 Q Okay. Well, let's go to DDX 7.15, and this is paragraph
01:14:59 20 249 from your expert report which is PX 183, and I'll just
01:15:04 21 read the first two sentences.

01:15:07 22 "Indeed, the labeling does not suggest in any
01:15:09 23 section that the drug should not be used, e.g., for
01:15:12 24 safety reasons, unless a patient has been placed
01:15:16 25 successfully on a diet for a specific amount of time.

01:15:20 1 If FDA had determined that safety or efficacy
01:15:23 2 concerns required pretreatment diet changes or
01:15:28 3 stabilization prior for a particular period of time,
01:15:32 4 it would have so stated in the labeling."

01:15:35 5 Do you stand by those two sentences from your
01:15:37 6 expert report?

01:15:38 7 A Yeah. Yes, I do. And I think the conditions under which
01:15:41 8 it would have occurred would be the ones that I described.

01:15:45 9 Of course, that's a hypothetical. It didn't -- this
01:15:49 10 isn't the case. We're not talking about the approved Vascepa
01:15:53 11 label, we're talking about hypotheticals.

01:15:56 12 Q So you're -- are you saying that paragraph 249 is a
01:16:10 13 hypothetical and not pertaining to the Vascepa label?

01:16:13 14 A Well, the first two sentences are sort of a general
01:16:16 15 hypothetical, yes.

01:16:19 16 Q Do you have the report in front of you?

01:16:29 17 A I don't think I do.

01:16:30 18 Q Why don't we pull it up. Let's go to PX 183, paragraph
01:16:39 19 248, the paragraph before this one.

01:16:43 20 Okay. And do you see here -- and actually I think
01:17:00 21 we read this earlier -- but you're referring specifically to
01:17:05 22 the Vascepa label. Do you see that in paragraph 248?

01:17:08 23 A Yes.

01:17:09 24 Q Okay. And then, if we go to the top of the next page so
01:17:18 25 we can see how the paragraph continues.

01:17:23 1 Okay. All right. So here -- can you put the whole
01:17:29 2 paragraph in one slide?

01:17:33 3 Okay. So in paragraph 248, and I won't read the
01:17:57 4 whole thing because we talked about some of this already --
01:18:00 5 you talked about how the Vascepa indication does not suggest
01:18:07 6 that Vascepa should be withheld until a patient has
01:18:10 7 successfully effected a change of diet. Do you see that?

01:18:14 8 A Yes.

01:18:14 9 Q Okay, and then you said,

01:18:16 10 "The only indication of timing is that the
01:18:19 11 usage considerations heading in the indications and
01:18:23 12 usage section and the dosage and administration
01:18:27 13 section recommend that a patient should be placed on
01:18:30 14 a diet before receiving Vascepa."

01:18:33 15 We talked about earlier, right?

01:18:35 16 A Yes.

01:18:36 17 Q Okay. But that's obviously referring to the specific
01:18:39 18 language in the Vascepa label, right?

01:18:43 19 A Yes, yes.

01:18:43 20 Q Then you say,

01:18:45 21 "But this is not a requirement. The use of
01:18:48 22 should leaves discretion, and it does not state how
01:18:51 23 long diet should precede prescription. As a result,
01:18:55 24 the labeling does not prevent physicians from,
01:18:57 25 consistent with established clinical practice,

01:19:00 1 discussing diet changes and prescribing Vascepa in
01:19:04 2 the same visit."

01:19:07 3 That's what you said in your report, right?

01:19:08 4 A Yes.

01:19:09 5 Q And then we go to paragraph 249, which is what we were
01:19:13 6 looking at before, and you start off by saying, "Indeed,"
01:19:18 7 you're referring to the labeling still, correct?

01:19:21 8 A Yeah.

01:19:22 9 Q The Vascepa labeling, that is, right?

01:19:24 10 A Well, I think the first -- I think the first and second
01:19:34 11 sentence really are a more general statement.

01:19:37 12 Q Well, let's take a look at it.

01:19:39 13 You say, "Indeed, the labeling," after you were just
01:19:43 14 talking about the Vascepa label, "does not suggest in any
01:19:47 15 section," you're talking about any section of the Vascepa
01:19:50 16 label, right?

01:19:51 17 A I think so, yes.

01:19:52 18 Q Yeah.

01:19:52 19 "That the drug should not be used, e.g., for
01:19:55 20 safety reasons unless a patient has been placed
01:19:59 21 successfully on a diet for a specific amount of
01:20:02 22 time," right?

01:20:03 23 A Yes.

01:20:03 24 Q Okay. And then you said,

01:20:05 25 "If FDA had determined that safety or

01:20:07 1 efficacy concerns required pretreatment diet changes
01:20:11 2 or stabilization prior for a particular period of
01:20:15 3 time, it would have so stated in the labeling,"
01:20:18 4 right?

01:20:18 5 You said that too --

01:20:18 6 A Yes.

01:20:18 7 Q -- in your report?

01:20:22 8 A Yes, I did.

01:20:22 9 Q And then you went on to give an example. Right? You
01:20:22 10 say,

01:20:25 11 "For example, the dosage and administration
01:20:27 12 section of the labeling for Alimta instructs that
01:20:31 13 physicians must initiate folic acid pretreatment for
01:20:35 14 a full seven days before the first dose of Alimta to
01:20:40 15 avoid increased risk of myelosuppression, i.e., bone
01:20:45 16 marrow suppression," correct.

01:20:47 17 A Yes.

01:20:47 18 Q Okay. And you stand by those sentences from your report?

01:20:50 19 A Well, I do, but what I'm trying to contrast was the --
01:20:58 20 was the motivation for establishing such a limitation is
01:21:04 21 highly dependent upon the condition being treated and the
01:21:08 22 drug.

01:21:08 23 In the case of my example, we have a
01:21:11 24 life-threatening condition that requires a -- generally a
01:21:21 25 chemotherapeutic agent, and in order to safely give that, the

01:21:26 1 folic acid is necessary as pretreatment.

01:21:29 2 So as I stated earlier if for safety reason or for
01:21:35 3 efficacy reasons it's required to be there, it should be
01:21:38 4 there.

01:21:39 5 Q Right. If there's -- if there's a reason to narrow the
01:21:42 6 patient population until after some initial treatment by a
01:21:49 7 different treatment, the label would say that, correct?

01:21:52 8 A Yes.

01:21:52 9 Q That's the point you're making.

01:21:54 10 A Again, there's -- it's a judgment that FDA makes. And in
01:22:03 11 the Alimta, I guess is the way you pronounce that, is an
01:22:08 12 extreme case, but it's a common one in which that kind of
01:22:11 13 limitation or advisory would be included in the label.

01:22:14 14 Q Right. It's common -- if FDA wants to limit a patient
01:22:18 15 population, it will explain how to limit the patient
01:22:21 16 population, such as, for example, treating the patient with a
01:22:26 17 different agent for a particular period of time before taking
01:22:29 18 the drug at issue, correct?

01:22:30 19 A Yes. Well said.

01:22:32 20 Q Okay. And let's take look at DDX 7.16 just to close this
01:22:41 21 out.

01:22:42 22 This is -- do you recognize PX 763 as the Alimta
01:22:51 23 label you were just referring to?

01:22:52 24 A Yes.

01:22:53 25 MR. KLEIN: All right. I'll move into evidence

01:22:55 1 PX 763.

01:22:59 2 MR. M. KENNEDY: No objection, Your Honor.

01:23:00 3 THE COURT: 763 is admitted.

01:23:00 4 (Plaintiffs' Exhibit 763 received in
01:23:02 evidence.)

01:23:02 5 BY MR. KLEIN:

01:23:03 6 Q And this -- the highlighted bullet is what you were
01:23:05 7 referring to earlier in your testimony, in the dosage and
01:23:08 8 administration section of Alimta, the label says initiate
01:23:13 9 folic acid beginning seven days prior to the first dose of the
01:23:17 10 drug, right?

01:23:18 11 A Yes.

01:23:18 12 Q Okay. And the Alimta label supports your opinion that if
01:23:24 13 FDA had determined safety or efficacy concerns, require
01:23:30 14 pretreatment diet changes, or stabilization prior to icosapent
01:23:35 15 use for a particular period of time, FDA would have so stated
01:23:39 16 in labeling, correct?

01:23:41 17 A Yes, if it's truly a critical matter.

01:23:44 18 Q Okay. Now, other sections of the labeling, we talked
01:23:50 19 about the -- well, let's back up.

01:23:53 20 Just to wrap this up, the indications and usage
01:23:56 21 section and the dosage and administration section, neither
01:24:01 22 section specifies any specific treatment duration, correct?

01:24:05 23 A There is not a specific statement with respect -- to that
01:24:11 24 effect.

01:24:11 25 Q And other sections of the labeling cannot imply or

01:24:15 1 suggest alternative dosing regimens not stated in the dosage
01:24:19 2 and administration section, correct?

01:24:23 3 A That's correct.

01:24:24 4 Q Now, on direct, you testified that doctors read the
01:24:34 5 labeling as a whole, right?

01:24:35 6 A That's true.

01:24:36 7 Q And reading defendants' labels as a whole allows
01:24:41 8 physicians to exercise their discretion as to both the timing
01:24:45 9 and content of any diet counseling.

01:24:47 10 Do you agree with that?

01:24:48 11 A I agree with that.

01:24:49 12 Q And there's no minimum or maximum therapy duration
01:24:53 13 anywhere in defendants' labels, correct?

01:24:55 14 A That's correct.

01:24:56 15 Q And so your opinion is simply that defendants' labels
01:25:01 16 implicitly instruct doctors that icosapent can be used
01:25:06 17 long-term, right?

01:25:08 18 A I'm not sure I'd say the label is instructing, you know
01:25:13 19 as sort of such a strong -- but it certainly encourages that,
01:25:17 20 yes.

01:25:17 21 Q Okay. So let me rephrase the question.

01:25:19 22 Your opinion is that defendants' labels are
01:25:22 23 implicitly encouraging doctors and informing them that
01:25:29 24 icosapent can be used long-term, correct?

01:25:32 25 A Yes.

01:25:32 1 Q But to be clear, there's no statement anywhere in
01:25:35 2 defendants' labels requiring doctors to use icosapent for at
01:25:40 3 least 12 weeks, correct?

01:25:43 4 A The word requirement is not included in the label.

01:25:47 5 Q Okay. And there's no explicit statement anywhere in the
01:25:51 6 label teaching doctors that they should use Vascepa long-term.
01:25:56 7 You're just saying that is implied, correct?

01:25:58 8 A Well, it's implied, and the audience would know that, you
01:26:03 9 know, the prescriber would know that in advance of reading the
01:26:08 10 label.

01:26:09 11 Q Okay. But just to be clear, your opinion is that it's
01:26:18 12 implied by the various sections of the label that doctors can
01:26:25 13 use Vascepa long-term, correct?

01:26:29 14 A Yes. I mean, implied -- I'm not sure that's the right
01:26:33 15 word, but according to the FDA's rules for labeling, if the
01:26:38 16 drug -- if there is no safety or efficacy reason for limiting
01:26:41 17 the duration, it should not be included in the label, and
01:26:44 18 that's meant to encourage the physician to use it as long as
01:26:48 19 they feel it's important for the patient.

01:26:50 20 Q Exactly. We'll get back to that testimony, but before we
01:26:54 21 do, just to be clear, defendants' labels never say that
01:26:58 22 icosapent is safe and effective only if administered for at
01:27:02 23 least 12 weeks, correct?

01:27:04 24 A I would agree with that.

01:27:06 25 Q Okay. And defendants' labels never mention a genetic

01:27:11 1 component associated with severe hypertriglyceridemia,
01:27:15 2 correct?

01:27:15 3 A I don't think so.

01:27:18 4 Q Let me rephrase the question because -- you're agreeing
01:27:21 5 with me, right?

01:27:22 6 A I'm agreeing with you, yes.

01:27:24 7 Q Okay. All right.

01:27:25 8 Instead, defendants' labels leave it entirely up to
01:27:29 9 doctors' discretion to decide how long to use icosapent,
01:27:34 10 correct?

01:27:35 11 A The label encourages at least 12 weeks, I believe, but
01:27:43 12 the physician can make his or her own decision.

01:27:48 13 Q You agree that the Vascepa label leaves it up to the
01:27:52 14 discretion of the doctor to determine the duration of
01:27:55 15 treatment, correct?

01:27:56 16 A I think I just explained what my view is.

01:27:59 17 MR. KLEIN: Okay. Let's play page 141, 25, to
01:28:05 18 142, line 3, please.

01:28:08 19 (Deposition video recording played.)

01:28:19 20 BY MR. KLEIN:

01:28:19 21 Q And just so the record is clear, you testified at
01:28:22 22 deposition that you agreed that the Vascepa label leaves it up
01:28:25 23 to the discretion of the doctor to determine the duration of
01:28:29 24 treatment, correct?

01:28:29 25 A So maybe we should look at the record again and see what

01:28:33 1 preceded that and what followed that because --

01:28:35 2 Q Doctor, all I asked you --

01:28:36 3 A -- it's possible that I qualified that just as I've been
01:28:40 4 qualifying it to you.

01:28:41 5 Q Okay. And, if so, your counsel can redirect. But all I
01:28:43 6 asked you is did you give that testimony at the deposition.

01:28:47 7 A Well, we heard the same thing I think. My hearing aids
01:28:49 8 may not be perfect, but it comes in louder than I want.

01:28:53 9 Q So that was your testimony, correct?

01:28:55 10 A Yes.

01:28:57 11 Q And the Vascepa labeling encourages physicians to
01:29:01 12 exercise their wide clinical discretion regarding not only the
01:29:05 13 content, but also the timing of any dietary recommendations,
01:29:10 14 correct?

01:29:10 15 A Yes. But it just doesn't leave it. It -- you know,
01:29:17 16 there's -- you have to take the label as a whole and interpret
01:29:22 17 it that way.

01:29:23 18 Q I'm sorry, I didn't catch --

01:29:25 19 A I said a physician should make decisions on the basis of
01:29:31 20 the label as a whole. So you continue to cite sort of single
01:29:36 21 sentences, and I think there's qualifications that relate to
01:29:39 22 many of these.

01:29:41 23 Q All right. Let's go to DDX 7.21, and this is paragraph
01:29:53 24 69 of your report PX 183, it's page 27.

01:30:00 25 And in this paragraph, you're responding to

01:30:04 1 Mr. Mathers in the middle of it, and you say,

01:30:07 2 "The Vascepa labeling encourages physicians
01:30:10 3 to exercise their wide clinical discretion regarding
01:30:14 4 the timing and content of any dietary
01:30:18 5 recommendations."

01:30:19 6 Do you see that in your report?

01:30:20 7 A Yes, I do.

01:30:21 8 Q Okay. When you say the Vascepa labeling, you were not
01:30:24 9 limiting it to any specific portion of the Vascepa label,
01:30:28 10 correct?

01:30:28 11 A Well, I mean, we were actually talking about a particular
01:30:31 12 kind of diet at the time, the questioned diet, and then the
01:30:36 13 words that follow, I think I qualify what I think the label is
01:30:42 14 trying to convey, and, that is, it encourages administration
01:30:46 15 of the drug when a patient who remained on or reverted to a
01:30:51 16 diet during treatment.

01:30:52 17 Q Okay. But when you said,

01:30:53 18 "The Vascepa labeling encourages physicians
01:30:57 19 to exercise their wide clinical discretion regarding
01:31:00 20 the timing and content of any dietary
01:31:04 21 recommendations,"

01:31:04 22 you were referring to the Vascepa labeling as a whole,
01:31:07 23 correct?

01:31:07 24 A Yes.

01:31:08 25 Q Okay. And so whether a physician prescribes Vascepa for

01:31:13 1 12 weeks, 24 weeks, or even just three weeks, any of those
01:31:17 2 uses would fall within the scope of FDA's approval. You agree
01:31:21 3 with that, right?

01:31:22 4 A Do you know the approval was actually based upon a
01:31:29 5 12-week clinical trial which demonstrated that patients with
01:31:34 6 hypertriglyceridemia had a 33 percent or greater decrease.

01:31:42 7 The 12-week trial was no accident. FDA felt that
01:31:48 8 12 weeks -- or agreed with the sponsor that 12 weeks was
01:31:53 9 sufficiently long to ascertain the benefit of the drug.

01:31:57 10 So, you know, despite the interpretation of the
01:32:07 11 label that it is permissive, nonetheless, when a physician
01:32:17 12 reads a label, the physician has to make a decision in writing
01:32:22 13 a prescription how long to treat.

01:32:23 14 What other guidance would the physician have if they
01:32:23 15 didn't go to the clinical study section and look and see what
01:32:32 16 the clinical trial showed.

01:32:32 17 Q Okay. Let's go --

01:32:33 18 A So I think there's encouragement to treat for at least 12
01:32:37 19 weeks.

01:32:37 20 Q Okay. And you used the word permissive in your answer.
01:32:40 21 What did you mean by that?

01:32:42 22 A I think we've discussed this before. The physician reads
01:32:45 23 the label and draws from the label what's relevant to the
01:32:48 24 physician.

01:32:49 25 The FDA guides the label to encourage best

01:32:53 1 practices. So since FDA does not regulate the practice of
01:33:01 2 medicine, doesn't regulate doctors, the label is a -- is a
01:33:09 3 reference that encourages good practice. But if you want to
01:33:14 4 say it's permissive, that's fine with me.

01:33:18 5 Q And let's go to DDX 7.22. This is paragraph 191 from
01:33:27 6 your expert report, which is PX 183, pages 82 and 83.

01:33:35 7 And if you go to the third sentence which I
01:33:41 8 highlighted, you said,

01:33:42 9 "Vascepa is approved for an indication and
01:33:45 10 dosing regimen that is not limited in duration.
01:33:50 11 Thus, whether a physician prescribes Vascepa for 12
01:33:53 12 weeks, 24 weeks, or even just three weeks, any such
01:33:57 13 use would be within the scope of FDA's approval, in
01:34:01 14 other words, because FDA approved Vascepa without
01:34:04 15 specifying any minimum or maximum duration of use,
01:34:08 16 use for any period of time is consistent with the
01:34:11 17 labeling."

01:34:11 18 That's an accurate statement, correct?

01:34:13 19 A Yes, and I agree with that statement.

01:34:22 20 Q And so defendants' indication covers or includes
01:34:25 21 short-term use of Vascepa, correct?

01:34:28 22 A Well, there's no information in the drug label that would
01:34:34 23 encourage that.

01:34:35 24 Q Well, that's not my question. The scope of the FDA
01:34:40 25 approval includes short-term use of Vascepa, correct?

01:34:43 1 A I think FDA's approval was based upon the 12-week -- the
01:34:48 2 demonstration of the safety and effectiveness in that 12-week
01:34:52 3 clinical trial.

01:34:52 4 Q Okay. Let --

01:34:53 5 A The label does not provide any additional information
01:34:57 6 with respect to shorter or longer periods of time, but it's
01:35:04 7 certainly not restrictive with respect to treating beyond
01:35:08 8 12 weeks.

01:35:08 9 Q Okay. It's not restrictive with regard to treating for
01:35:12 10 less than 12 weeks either, correct?

01:35:14 11 A No. It would not -- well, there's nothing in the label
01:35:17 12 that would -- that would encourage that.

01:35:19 13 Q Okay. But you agree that FDA put no limitation on the
01:35:23 14 duration of use, correct?

01:35:26 15 A You know, there's no limitations of use in the
01:35:33 16 indications and usage section or elsewhere that would do that.
01:35:37 17 Yes, I agree with that.

01:35:38 18 Q Okay. And the label expresses no preference for any
01:35:42 19 particular treatment duration, correct?

01:35:44 20 A Well, it -- you know, it -- it may be in the eyes of the
01:35:49 21 beholder. But, as I said, the fact that the drug was used for
01:35:55 22 12 weeks in a clinical trial and demonstrated effectiveness,
01:35:59 23 and that was FDA's basis for approval, and a physician reading
01:36:03 24 that would know that treating for at least 12 weeks would --
01:36:06 25 would accomplish the intent of treating hypertriglyceridemia.

01:36:12 1 Q All right. Just to be clear, the labeling is telling
01:36:16 2 doctors that they can use the drug for 12 weeks or longer if
01:36:20 3 they want, but it's not saying that they should. The label is
01:36:23 4 leaving it up to the discretion of the doctor as to the
01:36:26 5 duration for a particular patient, correct?

01:36:29 6 A I agree with that.

01:36:31 7 Q And so a doctor could prescribe icosapent for only ten
01:36:40 8 weeks, stop the treatment, have the patient maintain levels
01:36:44 9 below 500 with diet and exercise alone, and that would fall
01:36:49 10 within the scope of the FDA's approval correct?

01:36:54 11 A Well, FDA did not observe of that set of the data so it
01:36:59 12 didn't approve it on that basis.

01:37:01 13 Q Well, I didn't ask whether they approved it on that
01:37:04 14 basis, but that type of scenario where a doctor tells a
01:37:08 15 patient take Vascepa for ten weeks, improve your lifestyle
01:37:11 16 changes, and if you're below 500 in ten weeks, you can stop
01:37:15 17 the medication, but you need to keep the diet and exercise to
01:37:19 18 stay below 500, that type of activity by a doctor would be
01:37:25 19 consistent with the Vascepa labeling, correct?

01:37:27 20 A Well, in the practice of medicine that would be a
01:37:30 21 permitted practice.

01:37:31 22 Q But it would be consistent with the Vascepa labeling as
01:37:34 23 well, correct?

01:37:35 24 A I don't think the Vascepa labelling is sufficiently
01:37:40 25 informative to endorse that.

01:37:42 1 Q But it would be within the scope of what FDA-approved.
01:37:45 2 That would not be an off-label use, to use your terminology
01:37:50 3 from direct, correct?

01:37:51 4 A Sir, I never used the term off-label use. I used the
01:37:55 5 word off-label advertising.

01:37:58 6 Q Okay. All right.

01:37:59 7 If a doctor gave a patient Vascepa for ten weeks,
01:38:03 8 told them -- after ten weeks lipids are below 500, the doctor
01:38:08 9 said you can stop taking four pills a day, but you need to
01:38:12 10 keep dieting and exercising to maintain levels below 500, that
01:38:16 11 type of instruction from the doctor to the patient would be
01:38:19 12 consistent with the scope of FDA's approval for Vascepa,
01:38:24 13 correct?

01:38:24 14 A You know, when you say scope of FDA's approval, as a
01:38:29 15 regulatory expert, FDA approves a drug on the basis of the
01:38:33 16 evidence presented in the clinical trial that it accepts.

01:38:37 17 So the particular scenario you just described is not
01:38:42 18 an endpoint in that trial. It's not, you know, to my reading
01:38:47 19 of the clinical study group section of the FDA review, an
01:38:53 20 endpoint that FDA focused on.

01:38:56 21 So if you want to say that the physician has the
01:39:00 22 discretion to do that, despite encouragement in the label that
01:39:05 23 12 weeks would be a good time to evaluate the outcome of
01:39:08 24 therapy, I can accept that.

01:39:10 25 Q Okay. In fact, I can name a thousand different

01:39:13 1 durations, and they would all be decisions that the physician
01:39:17 2 could make for whatever reason that would not be inconsistent
01:39:20 3 with the label, correct?

01:39:22 4 A Well, those are decisions that the physician could make,
01:39:27 5 yes.

01:39:27 6 Q Okay.

01:39:28 7 A Consistency with the label seems to me that's a pretty
01:39:33 8 strong sort of linkage that you're trying to establish there,
01:39:36 9 and so absent information about anything outside of 12 weeks
01:39:41 10 or longer, it's -- it's an arguable point.

01:39:48 11 MR. KLEIN: All right. Okay. Mr. Gross, can
01:39:49 12 you play page 143, lines 13 to 22, please.

01:39:54 13 (Deposition video recording played.)

01:40:23 14 BY MR. KLEIN:

01:40:30 15 Q Doctor, did you give that testimony?

01:40:31 16 A I did.

01:40:34 17 MR. KLEIN: Okay. Your Honor, can I pause for
01:40:36 18 one second to raise a housekeeping issue. I've noticed that
01:40:40 19 in the transcript when we play the videos there's no
01:40:43 20 transcription of the actual Q and A from the transcript and
01:40:47 21 I've seen this before. What we typically do is attach the
01:40:51 22 relevant portions of the transcript to -- the deposition
01:40:54 23 transcript to the trial transcript, and if that's acceptable,
01:40:59 24 I won't read the question and answer again to make sure it's
01:41:02 25 in the record.

01:41:06 1 THE COURT: So where the transcript is played,
01:41:09 2 the court reporter will not transcribe what's being played.

01:41:13 3 MR. KLEIN: Right.

01:41:15 4 THE COURT: So I'm trying to understand your
01:41:17 5 issue. Some parts of the deposition video that's been played
01:41:20 6 I can see the transcription written out. But that
01:41:24 7 transcription is not part of the record either.

01:41:25 8 MR. KLEIN: Right. But it's a prior statement
01:41:27 9 under oath so it comes into evidence, and if it's not in the
01:41:32 10 trial transcript, then the deposition testimony isn't in the
01:41:37 11 record.

01:41:38 12 And so what I've done in the past is we've
01:41:41 13 attached the relevant portions of the deposition transcript
01:41:44 14 that were played to the end of the trial transcript to make it
01:41:49 15 clear what was played.

01:42:44 16 THE COURT: I think I understand the issue, and
01:42:46 17 I think we have a solution.

01:42:47 18 Mr. Klein, your concern, and I think this has
01:42:51 19 been throughout, is that where deposition testimony has been
01:42:55 20 played to either impeach as a prior inconsistent statement
01:43:00 21 or -- well, it's mostly that, not to refresh recollection,
01:43:03 22 that you want the record to reflect what that is for the
01:43:06 23 purposes of appellate review; is that right?

01:43:09 24 MR. KLEIN: Correct. Right.

01:43:09 25 THE COURT: So I'm told that you -- we can do

01:43:13 1 this at the end of the trial where you lodge the actual
01:43:16 2 deposition transcript as part of the record so that it's
01:43:19 3 available for appellate review.

01:43:22 4 So I want counsel to confer with Peggie at the
01:43:26 5 end the trial for the process of doing that. If you have an
01:43:29 6 issue, then I'll intervene, but otherwise this is how we would
01:43:32 7 handle it.

01:43:33 8 I'm not too familiar with what the court of
01:43:36 9 appeals does when it looks at our record, I'm told that the
01:43:40 10 transcript is lodged for them and made available for appellate
01:43:43 11 review.

01:43:43 12 MR. KLEIN: Okay. And just to be -- it's more
01:43:44 13 than appellate review, it's for your review as well because it
01:43:48 14 becomes evidence, the testimony becomes evidence that you can
01:43:50 15 rely on as well.

01:43:52 16 And I'm sorry to interrupt the
01:43:54 17 cross-examination, but otherwise I would have to play it and
01:43:57 18 then actually read it into the record.

01:43:58 19 THE COURT: I understand. Thank you.

01:44:00 20 MR. KLEIN: Okay.

01:44:01 21 THE WITNESS: Would you mind replaying that? I
01:44:04 22 just want to be sure that in the end the statement was scope
01:44:10 23 of approval or scope of label?

01:44:16 24 THE COURT: Well, Mr. Klein, why don't we do
01:44:18 25 this, if you have the deposition transcript that you want to

01:44:24 1 show Dr. Peck, that might help.

01:44:24 2 BY MR. KLEIN:

01:44:28 3 Q You should have a copy of the transcript, but the
01:44:32 4 testimony is what it is, and I'm not asking you to clarify the
01:44:39 5 testimony.

01:44:39 6 All I asked you is whether -- all I asked you was
01:44:43 7 whether you gave that testimony at the deposition, and if your
01:44:46 8 counsel wants to follow up they're free to follow up on
01:44:48 9 redirect.

01:44:50 10 A Well I'm just concerned that there's a difference between
01:44:53 11 scope of approval and scope of the label.

01:44:56 12 THE COURT: So, Dr. Peck, did you want to see
01:44:58 13 your answer? Is that issue?

01:44:58 14 THE WITNESS: Yes.

01:44:59 15 MR. KLEIN: Okay.

01:44:59 16 THE COURT: Let him see the answer.

01:45:02 17 MR. KLEIN: Do you have the transcript? Do you
01:45:02 18 have the deposition there? Well, we can play it again. Why
01:45:06 19 don't we play it again.

01:45:07 20 (Deposition video recording played.)

01:45:43 21 THE WITNESS: Okay. Just to clarify, I was
01:45:45 22 answering before --

01:45:46 23 MR. KLEIN: Well --

01:45:47 24 THE COURT: Hang on, Dr. Peck. There's no
01:45:49 25 question pending.

01:45:50 1 Would you identify for me again what page and
01:45:53 2 line number?

01:45:54 3 MR. KLEIN: Sure. It is page 143, lines 13 to
01:45:58 4 22.

01:45:58 5 THE COURT: All right. Dr. Peck, wait for the
01:46:01 6 question.

01:46:01 7 BY MR. KLEIN:

01:46:06 8 Q Okay. With regard to the answer you just gave, and maybe
01:46:10 9 you can answer my -- I know you want to say something, and
01:46:14 10 maybe your statement will be responsive to this question,
01:46:18 11 maybe not, but you said a doctor could even prescribe
01:46:22 12 icosapent for only three weeks and it would not be
01:46:25 13 inconsistent with the label, correct?

01:46:27 14 A That's correct.

01:46:28 15 Q And even with just three weeks, there can be many reasons
01:46:31 16 for a doctor to prescribe icosapent for only three weeks,
01:46:35 17 right?

01:46:35 18 A I don't know if there are many reasons. There could be.
01:46:40 19 I'm not testifying as a clinician experienced with this
01:46:43 20 condition.

01:46:44 21 Q But three weeks would not be a bad time to check whether
01:46:48 22 the drug was working or not, correct?

01:46:51 23 A I don't think the label encourages that.

01:46:55 24 MR. M. KENNEDY: Objection, this is getting
01:46:57 25 outside of the scope of his proffer as an FDA expert.

01:47:01 1 THE COURT: And Dr. Peck did just clarify that
01:47:04 2 he's not here to testify as a clinician.

01:47:06 3 MR. KLEIN: All right. I'll move on then.

01:47:08 4 BY MR. KLEIN:

01:47:11 5 Q Let's turn to the clinical study section. You talked
01:47:14 6 about that on direct, right?

01:47:16 7 A Yes.

01:47:16 8 Q Let's go to DDX 7.24.

01:47:27 9 So DDX 7.24. Okay. On the screen are two FDA
01:47:40 10 regulations, 21 CFR section 201.57(c)(2), and 21 CFR
01:47:49 11 section 201.57(c)(15).

01:47:53 12 You're familiar with these two regulations, right?

01:47:56 13 A In general, yes.

01:47:58 14 Q And generally speaking, these regulations say that
01:48:02 15 indications or uses must not be implied or suggested in other
01:48:07 16 sections of the labeling if not included in this section.
01:48:11 17 That's 57(c)(2) for indications, right?

01:48:16 18 A Yes.

01:48:17 19 Q And for the clinical studies regulation, which is
01:48:22 20 (c)(15), it similarly says that you shouldn't imply -- you
01:48:29 21 must not imply or suggest indications or uses or dosing
01:48:33 22 regimens not stated in the indications and usage or dosage and
01:48:37 23 administration section from the clinical study section,
01:48:41 24 correct?

01:48:42 25 A Correct.

01:48:43 1 MR. KLEIN: And let's go to DDX 7.25.

01:48:43 2 BY MR. KLEIN:

01:48:49 3 Q All right. So this is -- on the top I have the
01:48:54 4 regulation (c) (2) (4) which we just looked at which says
01:48:59 5 indications or uses must not be implied or suggested in other
01:49:03 6 sections of the labeling if not included in this section.

01:49:06 7 And on the bottom, I have the clinical study section
01:49:11 8 from Hikma's proposed label which is DX 2256.

01:49:15 9 Do you see that?

01:49:15 10 A Yes. It's incomplete.

01:49:18 11 Q Right. Understood. And we'll talk about the other
01:49:22 12 portions of the clinical study section, but I just want to
01:49:27 13 focus for now on the statement that says patients were
01:49:30 14 enrolled in the study for 12 weeks.

01:49:33 15 Do you see that? It's highlighted.

01:49:37 16 A Give me a minute here.

01:49:39 17 Q Yeah.

01:49:42 18 A Yes, I do.

01:49:43 19 Q Okay. And so to be clear, the length of a clinical study
01:49:48 20 reported in the clinical study section is not supposed to
01:49:52 21 imply or suggest a particular dosing regimen that's not stated
01:49:56 22 in the dosage and administration section, correct?

01:49:59 23 A Yes.

01:50:00 24 Q And so what defendants' labels are doing in section 14.2
01:50:09 25 are describing the MARINE study which lasted 12 weeks, right?

01:50:14 1 A Yes.

01:50:15 2 Q And this 12-week study description is not implying that
01:50:21 3 doctors should prescribe icosapent for only 12 weeks, right?

01:50:26 4 A Well, I think it encourages to treat for at least
01:50:32 5 12 weeks or more.

01:50:33 6 Q Okay. But it's certainly not -- you can't reasonably
01:50:39 7 read 14.2 of defendants' label as saying, okay, the study was
01:50:44 8 12 weeks, therefore doctors should prescribe the drug for 12
01:50:48 9 weeks, no less, no more, correct?

01:50:50 10 A I would agree with that.

01:50:51 11 Q Okay. And the clinical study section, the fact that it
01:50:56 12 lasts -- that the clinical study discussed in the clinical
01:51:00 13 study section lasted for 12 weeks is informing doctors that
01:51:04 14 icosapent can be used for at least 12 weeks, right?

01:51:09 15 A Yes.

01:51:09 16 Q Okay. But a doctor would know from the label as a whole
01:51:12 17 that icosapent also can be used for shorter or longer
01:51:17 18 durations, correct?

01:51:18 19 A The doctor has the discretion to use the drug for as long
01:51:29 20 as he thinks is in the best interest of the patient absent a
01:51:34 21 limitation or any other advisory apart from the 12 weeks. I
01:51:40 22 agree with what you just said.

01:51:45 23 Q Now, let's go to DDX 7.34. And I want to focus on -- I'm
01:51:55 24 changing topics little bit. On direct you talked about apo B,
01:52:00 25 do you remember that?

01:52:01 1 A I do.

01:52:01 2 Q Okay. I've highlighted the apo B line in Table 2 of
01:52:04 3 Hikma's label which is DX 2256, pages 7 and 8. And I also
01:52:12 4 highlighted the relevant portion of the statement below the
01:52:15 5 chart that says,

01:52:16 6 "Icosapent ethyl 4 grams per day reduced
01:52:19 7 median apo B levels from baseline relative to
01:52:24 8 placebo."

01:52:25 9 Do you see that?

01:52:25 10 A Yes.

01:52:25 11 Q Okay. Just to be clear, FDA did not approve the Vascepa
01:52:30 12 indication to reduce apo B, correct?

01:52:33 13 A It approved Vascepa for the treatment of
01:52:37 14 hypertriglyceridemia while reducing apo B. This is clear in
01:52:42 15 the label.

01:52:42 16 Q The indicated use for Vascepa doesn't talk about apo B at
01:52:48 17 all, correct?

01:52:49 18 A I'm talking about the approved label and the approved
01:52:53 19 drug.

01:52:53 20 Q But -- well, let me rephrase the question.

01:52:55 21 FDA did not approve an indication for Vascepa that
01:53:00 22 has anything to do with apo B, correct?

01:53:02 23 A I don't agree with that at all.

01:53:05 24 Q Let's go to DDX 7.35. And, again, I want to refer back
01:53:13 25 to the regulation we looked at, 21 CFR 201.57(c)(2).

01:53:22 1 You agree the indication doesn't mention, doesn't
01:53:26 2 use the term apo B, correct?

01:53:28 3 A That's correct.

01:53:29 4 Q Okay. And you agree that indications or uses must not be
01:53:34 5 implied or suggested in other sections of the labeling if not
01:53:39 6 included in the indications section, correct?

01:53:44 7 A Right. But the meaning of this is that indications
01:53:46 8 independent of the main indication, or the one that was proven
01:53:51 9 under a -- a well-controlled trial, are not to be implied.

01:53:55 10 But when FDA considers it to be important to call
01:53:59 11 out, as it did in this case, that the apo B is significantly
01:54:03 12 reduced, it did so.

01:54:05 13 And so it would not be inappropriate to consider
01:54:10 14 this label as a whole to be approved for the use of treatment
01:54:14 15 of hypertriglyceridemia while reducing apo B.

01:54:18 16 Q And, Doctor, just to be clear, you're not offering
01:54:21 17 testimony that reducing apo B is in any way relevant to
01:54:28 18 addressing the severe hypertriglyceridemia condition, correct?

01:54:32 19 A So FDA did exactly that. It interpreted this information
01:54:40 20 and it called out that decrease. And so FDA approved this
01:54:48 21 label, it approved this drug for the treatment of
01:54:51 22 hypertriglyceridemia while reducing apo B.

01:54:57 23 Q Do you understand, Doctor, that reducing apo B is
01:55:01 24 something that persons of ordinary skill in the art will focus
01:55:06 25 on to address cardiovascular issues and not severe

01:55:09 1 hypertriglyceridemia?

01:55:11 2 MR. M. KENNEDY: Objection, outside the scope of
01:55:13 3 his direct and his proffer.

01:55:14 4 MR. KLEIN: Well, I actually want to establish
01:55:16 5 that he's not offering any opinion one way or the another on
01:55:19 6 that issue. So that's -- I agree with the objection --

01:55:21 7 MR. M. KENNEDY: That's where it's going --

01:55:21 8 BY MR. KLEIN:

01:55:23 9 Q To the extent that there's no -- you're not offering any
01:55:26 10 opinions on whether reducing apo B is relevant to treating
01:55:31 11 severe hypertriglyceridemia, correct?

01:55:33 12 A Only that --

01:55:33 13 THE COURT: Mr. Kennedy -- I'm sorry, Dr. Peck.
01:55:35 14 Mr. Kennedy, do you agree with that?

01:55:37 15 MR. M. KENNEDY: The second version of the
01:55:39 16 question is fine. The first version I thought was stated a
01:55:43 17 little more affirmatively. But if the only point is to
01:55:47 18 address that he's not offering those opinions, then I would
01:55:49 19 withdraw the objection.

01:55:49 20 BY MR. KLEIN:

01:55:50 21 Q Yeah. Do you want me to rephrase the question?

01:55:53 22 A Please.

01:55:53 23 Q You're not offering any opinion in this case that
01:55:56 24 reducing apo B relates to treating severe
01:56:01 25 hypertriglyceridemia, correct?

01:56:01 1 A My opinion is that FDA considered this to be an important
01:56:05 2 element to call out.

01:56:09 3 Now, FDA has physicians, it has lipidologists that
01:56:13 4 work there, so, you know, by implication, for some reason,
01:56:16 5 they thought this was an important call-out associated with
01:56:19 6 the reduction of severe hypertriglyceridemia. But, I
01:56:22 7 personally am simply interpreting what FDA did.

01:56:29 8 Q Okay. So I'm not sure you directly answered my question.

01:56:33 9 You're not offering any opinion in this case that
01:56:37 10 reducing apo B relates to treating severe
01:56:41 11 hypertriglyceridemia, correct?

01:56:41 12 A I don't know.

01:56:47 13 Q I think counsel stipulated to that so --

01:56:50 14 A I don't know. I'm --

01:56:51 15 THE COURT: So, Dr. Peck, to be fair, you're
01:56:53 16 only offering testimony with respect to the FDA's labeling
01:56:58 17 process and the label. You're not an expert in the other
01:57:00 18 areas; is that right?

01:57:01 19 THE WITNESS: That's correct. But I can notice
01:57:03 20 what FDA thought was important.

01:57:06 21 THE COURT: That's a different issue though, I
01:57:08 22 think.

01:57:08 23 MR. KLEIN: That's a different --

01:57:10 24 THE COURT: So why don't you listen to
01:57:13 25 Mr. Klein's question. He's not asking you what you think the

01:57:16 1 FDA is noticing, he's asking a broader question. Would you
01:57:19 2 answer his question.

01:57:20 3 BY MR. KLEIN:

01:57:20 4 Q The indication is limited to treating severe
01:57:24 5 hypertriglyceridemia, correct?

01:57:25 6 A In the indications --

01:57:27 7 Q In the indications section.

01:57:29 8 A Right. Right. Right. No, I wouldn't say it's limited.
01:57:33 9 That is the indication.

01:57:35 10 Q Okay. The indication is for treating patients with
01:57:38 11 severe hypertriglyceridemia, correct?

01:57:40 12 A Right.

01:57:40 13 Q And you're not offering any opinion in this case that
01:57:44 14 treating severe hypertriglyceridemia is relevant to reducing
01:57:49 15 apo B levels, correct?

01:57:52 16 A I suppose not.

01:57:54 17 Q Okay. Let me get to the last topic. You talked about
01:57:59 18 there's some claim limitations addressing concurrent lipid
01:58:05 19 altering medications. Do you remember that?

01:58:06 20 A Yes, I do.

01:58:07 21 Q All right. And defendants' labels do not specifically
01:58:10 22 encourage doctors and patients to use icosapent either with or
01:58:14 23 without a concurrent lipid-altering therapy, right?

01:58:17 24 A Would you repeat the question, please?

01:58:19 25 Q Sure. Defendants' labels do not specifically encourage

01:58:24 1 defendants -- I'm sorry. Defendants' labels do not
01:58:27 2 specifically encourage doctors and patients to use icosapent
01:58:31 3 either with or without a concurrent lipid-altering therapy,
01:58:35 4 correct?

01:58:36 5 A There's no specific statement to that effect, but I
01:58:39 6 believe it encourages monotherapy.

01:58:41 7 Q Okay. But defendants' labels don't express any
01:58:44 8 preference for taking icosapent with or without a statin, for
01:58:48 9 example, right?

01:58:49 10 A There is no explicit statement of a preference.

01:58:55 11 Q Okay. And the label as a whole is saying that Vascepa is
01:59:03 12 effective to reduce triglyceride levels in adult patients with
01:59:07 13 severe hypertriglyceridemia regardless of whether it's taken
01:59:10 14 with or without a statin, correct?

01:59:13 15 A The data supports that, but I believe it encourages
01:59:18 16 monotherapy.

01:59:19 17 MR. KLEIN: All right. Let's play 109,
01:59:22 18 page 109, line 17 to 22.

01:59:27 19 (Deposition video recording played.)

01:59:47 20 BY MR. KLEIN:

01:59:48 21 Q Was that your testimony at the deposition?

01:59:49 22 A Yes.

01:59:50 23 Q Okay. And there's no language in defendants' labeling --
01:59:54 24 labels identifying any benefit to taking icosapent without a
01:59:58 25 statin, right?

02:00:01 1 A I disagree with that statement.

02:00:08 2 MR. KLEIN: Okay. Let's pay 112, line 24 to
02:00:13 3 113, line 7.

02:00:13 4 (Deposition video recording played.)

02:00:16 5 BY MR. KLEIN:

02:00:40 6 Q Did you give that testimony at the deposition?

02:00:42 7 A Yes, I did.

02:00:43 8 Q Okay. So just to be clear, the label as a whole,
02:00:46 9 defendants' labels as a whole, teach that physicians should
02:00:49 10 use their discretion with respect to using a statin with
02:00:54 11 icosapent, correct?

02:00:55 12 A The label doesn't say anything about discretion. The
02:01:00 13 label as a whole places no limitation on use or nonuse.

02:01:08 14 But a physician reading the clinical study section
02:01:11 15 would recognize that because 75 percent of the patients in the
02:01:14 16 trial were not on a statin, this drug is effective for
02:01:19 17 monotherapy, and monotherapy is always preferred over
02:01:24 18 polytherapy.

02:01:26 19 MR. KLEIN: Let's play page 102, lines 14
02:01:31 20 through 19.

02:01:32 21 (Deposition video recording played.)

02:01:37 22 BY MR. KLEIN:

02:01:54 23 Q You gave that testimony at the deposition, right?

02:01:56 24 A Yes.

02:01:56 25 MR. KLEIN: Thank you. I have no further

02:01:58 1 questions at this time.

02:01:59 2 MR. M. KENNEDY: Your Honor, I just have a
02:02:01 3 little bit of redirect.

02:02:01 4 REDIRECT EXAMINATION

02:02:01 5 BY MR. M. KENNEDY:

02:02:21 6 Q So, Dr. Peck, do you recall Mr. Klein asking you about
02:02:25 7 patient subgroups who may or may not be identified in the
02:02:28 8 indications and usage section?

02:02:30 9 A Yes.

02:02:30 10 Q In general, what is a patient subgroup?

02:02:34 11 A Well, it would be a group of patients who shared a common
02:02:40 12 factor or a common feature that differentiated them from
02:02:47 13 everyone else in the larger group of patients who were
02:02:51 14 included in the clinical study.

02:02:53 15 MR. M. KENNEDY: Would it be possible to get
02:02:55 16 cross-demonstrative DDX 78 back on the screen? I'm not sure
02:03:03 17 who I should ask.

02:03:04 18 Ah. Yes.

02:03:04 19 BY MR. M. KENNEDY:

02:03:06 20 Q So, Dr. Peck, do you remember this demonstrative from
02:03:09 21 Mr. Klein's discussion?

02:03:11 22 A Yes.

02:03:12 23 Q And you see there's a discussion in this document about
02:03:15 24 selected patient subgroups are diseased subpopulations for
02:03:22 25 whom the drug is approved? Do you see that?

02:03:22 1 A Yes.

02:03:23 2 Q And, you know, for example, the last three lines, it
02:03:29 3 says,

02:03:29 4 "For example, if a drug is for use only in
02:03:32 5 patients with a history of coronary disease events,
02:03:36 6 i.e., a secondary prevention, the indication should
02:03:40 7 clearly convey the patient population for which the
02:03:43 8 drug is approved."

02:03:44 9 Do you see that?

02:03:44 10 A Yes.

02:03:45 11 Q Is a diet a patient is on before he or she develops very
02:03:50 12 high triglycerides or severe hypertriglyceridemia, does that
02:03:53 13 define a patient's subgroup?

02:03:57 14 A It wouldn't in my mind, in part because you wouldn't
02:04:05 15 know -- you wouldn't know that in advance. I mean, I think
02:04:08 16 this -- identification of a subgroup, you know, like age group
02:04:16 17 or gender, or, in this case, patients that had a history of
02:04:22 18 coronary, that's clearly something you can identify in advance
02:04:27 19 and then apply this, this limitation.

02:04:31 20 But I think it stretches the point that whether or
02:04:36 21 not you can stay on a diet can be predicted in advance or
02:04:40 22 really is a clear patient subgroup.

02:04:44 23 MR. M. KENNEDY: Could I have PX 1186, the
02:04:47 24 current Vascepa label.

02:04:49 25 THE CLERK: Switching it to Plaintiffs'

02:04:54 1 (inaudible) .

02:04:54 2 MR. M. KENNEDY: Thank you. Mr. Brooks, could
02:04:56 3 you blow up -- would it be possible to blow up sections 1 and
02:05:01 4 2 in the full prescribing information?

02:05:01 5 BY MR. M. KENNEDY:

02:05:05 6 Q So, Dr. Peck, do you remember some discussion with
02:05:08 7 Mr. Klein about whether the indication of Vascepa is limited
02:05:12 8 to patients based on the diet that they're on when they get
02:05:16 9 severe hypertriglyceridemia? Do you remember that testimony?

02:05:19 10 A Yes, I did, I do.

02:05:21 11 Q Is the indication limited to any particular diet for the
02:05:25 12 patient who has severe hypertriglyceridemia?

02:05:30 13 A Well, I don't think I see a clear limitation. There's an
02:05:44 14 encouragement to use an appropriate diet.

02:05:48 15 Q Well, let me direct you to the Dosage and Administration
02:05:52 16 Section, section 2.1.

02:05:55 17 And, Dr. Peck, in the context of this label, what
02:05:59 18 does it mean when the label says "prior to initiation of
02:06:03 19 Vascepa"?

02:06:05 20 A Well, I think it would mean --

02:06:14 21 Q What does prior --

02:06:16 22 A It would be a date or period of time in advance of
02:06:18 23 initiating Vascepa therapy.

02:06:21 24 Q And am I correct that according to 2.1, the label is
02:06:28 25 instructing that patients should engage in appropriate

02:06:31 1 nutritional intake and physical activity before receiving
02:06:34 2 Vascepa?

02:06:35 3 A Yes.

02:06:37 4 MR. M. KENNEDY: Your Honor, could I have
02:06:38 5 indulgence to consult with my colleagues for just a second?

02:06:42 6 THE COURT: Yes.

02:06:48 7 (Discussion held off the record.)

02:06:48 8 MR. M. KENNEDY: Your Honor, nothing further.

02:06:51 9 MR. KLEIN: Nothing further from me.

02:06:53 10 THE COURT: Thank you, Dr. Peck. You may step
02:06:56 11 down.

02:07:21 12 (The witness was excused.)

02:07:21 13 MR. M. KENNEDY: Your Honor, Plaintiffs' next
02:07:23 14 call Dr. Sean Nicholson. And, again, may we approach to
02:07:28 15 distribute binders and slides?

02:07:30 16 THE COURT: Yes. Thank you.

02:07:30 17 SEAN NICHOLSON
02:07:30 18 called as a witness on behalf of the Plaintiffs,
02:07:30 18 was sworn and testified as follows:

02:07:57 19 THE CLERK: Please be seated.

02:07:58 20 Please state your name and spell both your first
02:08:02 21 name and last name for the record.

02:08:04 22 THE WITNESS: Sean Nicholson; S-e-a-n,
02:08:35 23 N-i-c-h-o-l-s-o-n.

02:08:39 24 MR. M. KENNEDY: Your Honor, may I proceed?

02:08:41 25 THE COURT: Yes.

DIRECT EXAMINATION

BY MR. M. KENNEDY:

Q Good afternoon, Dr. Nicholson. Are you currently employed?

A Yes, I am.

Q Where are you currently employed?

A Cornell University.

Q What is your position at Cornell?

A I'm a professor in the Department of Policy Analysis and Management.

Q What does that position involve at a high level?

A So I conduct research. I also teach, and I direct one of our graduate programs.

Q How long have you held -- how long have you been at Cornell?

A For 15 years.

Q Do you currently hold any other positions?

A Yes. I'm a research associate at the National Bureau of Economic Research, and I'm also an Associate Editor at a journal called *Health Economics*.

Q Could you describe your educational background.

A Yes. I graduated from Dartmouth College magna cum laude with a degree in economics, and then received a masters and a Ph.D. in economics from the University of Wisconsin at Madison.

02:09:46 1 Q When did you receive your Ph.D.?

02:09:47 2 A 1997.

02:09:49 3 Q How would you describe your research and teaching
02:09:53 4 specialty?

02:09:53 5 A I focus on the economics of healthcare and even more
02:09:57 6 specifically on economics of the biotech and pharmaceutical
02:10:01 7 industries.

02:10:02 8 Q How long have you specialized in this field?

02:10:05 9 A For over 25 years.

02:10:06 10 Q Could you go into a little more detail about the aspects
02:10:09 11 of the healthcare industry you specialize in in your research.

02:10:13 12 A Yes, I specialize in analyzing pharmaceutical
02:10:18 13 competition, pricing, and innovation.

02:10:20 14 Q And can you give an example of the type of project you've
02:10:23 15 handled in this area?

02:10:25 16 A Yes. Examples would include examining what types of
02:10:30 17 companies are most effective at getting their drugs approved
02:10:33 18 by the Food and Drug Administration, or why sometimes two or
02:10:36 19 more companies develop drugs together, or whether new
02:10:40 20 medicines which tend to be relatively expensive are worth it,
02:10:44 21 the value of new medicines.

02:10:46 22 Q Generally who funds your research?

02:10:48 23 A My research has been funded by agencies, including the
02:10:53 24 Robert Wood Johnson Foundation, the Centers For Disease
02:10:57 25 Control and Prevention, and also the Agency For Healthcare

02:11:02 1 **Research and Quality.**

02:11:03 2 Q Do you also teach students?

02:11:04 3 A I do. I'm currently teaching three courses. I teach an
02:11:08 4 undergraduate course, which is overview of the U.S. healthcare
02:11:11 5 system, and then I teach two graduate level courses, one on
02:11:15 6 healthcare finance and another on the pharmaceutical industry,
02:11:19 7 specifically pharmaceutical policy and management.

02:11:22 8 Q Do you publish?

02:11:23 9 A I do. I've published over 50 articles in peer review
02:11:28 10 journals and also have published some book chapters and was a
02:11:33 11 coeditor of the Handbook on the Economics of the
02:11:37 12 Biopharmaceutical Industry.

02:11:39 13 Q And when was that handbook published?

02:11:42 14 A That was 2012.

02:11:43 15 MR. M. KENNEDY: Mr. Brooks, can we please have
02:11:45 16 PX 1098.

02:11:45 17 BY MR. M. KENNEDY:

02:11:51 18 Q Dr. Nicholson, do you recognize this document?

02:11:53 19 A Yes, this is copy of my curriculum vitae or CV.

02:11:58 20 Q The CV is dated May 2019. Is this CV substantially
02:12:03 21 current as of today?

02:12:03 22 A Yes.

02:12:04 23 Q Does PX 1098 accurately reflect your educational and
02:12:08 24 professional experience?

02:12:09 25 A Yes, it does.

02:12:11 1 MR. M. KENNEDY: Your Honor, Amarin offers
02:12:13 2 PX 1098 into evidence.

02:12:17 3 MR. ROUNDS: No objection, Your Honor.

02:12:18 4 THE COURT: PX 1098 is admitted.

02:12:18 5 (Plaintiffs' Exhibit 1098 received in
02:12:21 evidence.)

02:12:21 6 MR. M. KENNEDY: And, Your Honor, we also offer
02:12:23 7 Dr. Nicholson as expert in the economics of the pharmaceutical
02:12:27 8 industry.

02:12:28 9 MR. ROUNDS: No objection, Your Honor.

02:12:29 10 THE COURT: The Court will certify Dr. Nicholson
02:12:32 11 as an expert on the economics of the pharmaceutical industry.

02:12:37 12 MR. M. KENNEDY: Mr. Brooks, can we please have
02:12:40 13 PDX 5-3.

02:12:40 14 BY MR. M. KENNEDY:

02:12:42 15 Q Dr. Nicholson, at a high level, what were you asked to do
02:12:45 16 in this case?

02:12:46 17 A My assignment was to assess whether Vascepa has been a
02:12:49 18 commercial success and whether there is a nexus between the
02:12:54 19 commercial success, if any, and the patented features there in
02:12:58 20 suit.

02:12:58 21 Q What's your understanding of Vascepa's indication?

02:13:03 22 A Initially, in 2012, Vascepa received an indication as a
02:13:08 23 method of reducing triglycerides or TG amongst patients with
02:13:13 24 severe hypertriglyceridemia, or very high TGs.

02:13:18 25 And then, in December of 2019, Vascepa received a

02:13:20 1 second indication of reducing major cardiovascular events
02:13:25 2 amongst patients with TG levels of 150 or above. So that
02:13:29 3 would include high and also very high TG patients.

02:13:34 4 Q Now, there's some discussion -- were you in the courtroom
02:13:36 5 this morning when Mr. Hofmann testified?

02:13:38 6 A Yes, I was.

02:13:39 7 Q And you recall there was some discussion about Vascepa's
02:13:43 8 current indication with Mr. Hofmann?

02:13:45 9 A Yes.

02:13:45 10 Q Does the new indication granted in December 2019 change
02:13:49 11 your opinions in any way?

02:13:51 12 A It strengthens my opinion. It doesn't change it. My
02:13:57 13 opinion is that Vascepa is commercially successful and that
02:14:00 14 was based on reports that I filed through, I believe, May
02:14:05 15 of 2019. The second indication would just strengthen that
02:14:08 16 opinion.

02:14:09 17 Q Now, for purposes of the opinions you developed, what's
02:14:12 18 your understanding of the patented feature?

02:14:15 19 A My understanding is that the patents practice a method of
02:14:21 20 reducing TG levels without increasing LDL-C or bad
02:14:25 21 cholesterol.

02:14:26 22 Q And where did you get that understanding from?

02:14:28 23 A From counsel.

02:14:29 24 Q And just to be clear, do you have any technical
02:14:32 25 background in lipid science, treatment of lipid diseases, or

02:14:36 1 treating severe hypertriglyceridemia?

02:14:38 2 A No, I do not.

02:14:39 3 Q So, in brief, why did you conclude that Vascepa is a
02:14:44 4 commercial success?

02:14:46 5 A So I examined Vascepa's performance in the marketplace,
02:14:51 6 and, more specifically, I looked at the number of
02:14:54 7 prescriptions that have been filled for Vascepa and the trend
02:14:57 8 in the number of prescriptions, also the amount of sales that
02:15:01 9 Amarin has collected for Vascepa and the trend in sales.

02:15:04 10 I looked at the market share of Vascepa so what
02:15:07 11 percentage of patients in different drug categories are taking
02:15:11 12 Vascepa relative to the other drugs, and the trend in market
02:15:15 13 share.

02:15:15 14 And then, finally, I conducted a lifecycle analysis
02:15:19 15 of Vascepa's profits.

02:15:21 16 Q And what's your understanding of what we mean by nexus in
02:15:24 17 the context of patent law and the commercial success analysis?

02:15:29 18 A My understanding is there's a nexus if the commercial
02:15:33 19 success is driven in part, is due in part to the patented
02:15:38 20 features.

02:15:39 21 Q And, at a high level, what did you conclude with respect
02:15:41 22 to nexus?

02:15:42 23 A I concluded that the Vascepa is commercially successful
02:15:46 24 and there a nexus between it's commercial success and the
02:15:50 25 patented features and that the success is not significantly

02:15:53 1 due to other factors such as promotion or marketing or
02:15:56 2 pricing.

02:15:57 3 MR. M. KENNEDY: Mr. Brooks, may we please have
02:15:59 4 PDX 5-4.

02:15:59 5 BY MR. M. KENNEDY:

02:16:02 6 Q So in the context of patent law, what's your
02:16:06 7 understanding of why a product's commercial success is
02:16:09 8 relevant to whether or not an invention is obvious at the time
02:16:12 9 it was made?

02:16:14 10 A Based on economics, you would expect inventions that have
02:16:18 11 commercial value, that are commercially successful to be
02:16:22 12 developed. So if we observe a situation where companies are
02:16:26 13 foregoing an opportunity to develop something that has
02:16:29 14 commercial value, then that provides evidence that the patents
02:16:32 15 aren't obvious.

02:16:33 16 Q And what sort of factors do you look at in analyzing
02:16:37 17 commercial success for purposes of a patent case?

02:16:40 18 A It depends on the case. In this particular case, as I
02:16:44 19 mentioned, what I looked at was prescriptions and trends in
02:16:48 20 prescriptions, sales, trends in sales of Vascepa, also market
02:16:53 21 share and trends in market share, and the Net Present Value or
02:16:56 22 the lifecycle profits analysis.

02:16:59 23 MR. M. KENNEDY: Mr. Brooks, can we have
02:17:02 24 PDX 5-5.

02:17:02 25

02:17:02 1 BY MR. M. KENNEDY:

02:17:04 2 Q And, Dr. Nicholson, is this a slide that you worked with
02:17:06 3 us to create to illustrate your opinions today?

02:17:09 4 A Yes, it is.

02:17:10 5 Q What are you showing on this slide?

02:17:12 6 A What I'm showing on the horizontal axis is the years
02:17:17 7 between 2008 and 2018, and then on the vertical axis is the
02:17:22 8 research and development spending that Amarin conducted for
02:17:27 9 Vascepa in millions of dollars.

02:17:30 10 So you can see the R&D costs or spending ranges from
02:17:33 11 eight million in 2008, all the way through 56 million in 2018.

02:17:38 12 Q And what's your understanding of when Amarin started
02:17:41 13 developing Vascepa?

02:17:43 14 A So the initial R&D expenditures were in 2008, and then
02:17:48 15 between 2009 and 2011, Amarin conducted two clinical trials,
02:17:55 16 the MARINE trial which focused on patients with very high TG
02:17:59 17 to see if Vascepa reduced TG in that patient population. The
02:18:03 18 ANCHOR trial -- that was the MARINE trial.

02:18:05 19 The ANCHOR trial focused on patients with high TG
02:18:09 20 levels to see whether Vascepa reduced TG in that patient
02:18:13 21 population, and those trials began in 2009 and concluded in
02:18:17 22 2011.

02:18:19 23 Q Does this slide PDX -- strike that.

02:18:22 24 What are the sources you used to put together PDX
02:18:27 25 slide 5-5?

02:18:28 1 A So this figure was produced with data from financial
02:18:31 2 statements that Amarin filed with the SEC, specifically the
02:18:34 3 documents that are enumerated at the bottom.

02:18:38 4 MR. M. KENNEDY: Your Honor, we would like to
02:18:39 5 offer PDX 5-5 as a summary exhibit pursuant to FRE 1006.

02:18:48 6 MR. ROUNDS: No objection, Your Honor.

02:18:49 7 THE COURT: Are you also moving to admit the
02:18:51 8 underlying documents which is PX 590 and 632?

02:18:58 9 MR. M. KENNEDY: I can. I don't believe there's
02:19:00 10 an objection, so I would also move PX 590 and PX 632.

02:19:05 11 THE COURT: Any objection?

02:19:06 12 MR. ROUNDS: No objection, Your Honor.

02:19:07 13 THE COURT: All right. All three documents are
02:19:08 14 admitted.

02:19:08 15 (Plaintiffs' Exhibits 5-5 and 632
02:19:08 received in evidence.)

02:19:08 16 BY MR. M. KENNEDY:

02:19:11 17 Q So, Dr. Nicholson, how much did Amarin spend on R&D
02:19:15 18 between 2008 and 2018?

02:19:17 19 A So Amarin spent almost half a billion dollars, so
02:19:22 20 465,000,000, and I should point out that between 2011 and 2018
02:19:28 21 Amarin was conducting the REDUCE-IT trial so that trial
02:19:32 22 followed about 8,000 patients with high TG levels to determine
02:19:37 23 whether or not Vascepa would reduce the probability of major
02:19:43 24 cardiovascular events.

02:19:44 25 Q And this slide, PDX 5-5 doesn't include Amarin's R&D

02:19:49 1 spending for 2019 or later; is that right?

02:19:51 2 A That's correct, it's just through 2018.

02:19:54 3 Q Is all the R&D spending reflected on PDX 5-5 attributable
02:20:01 4 to Vascepa?

02:20:02 5 A Yes, it is.

02:20:04 6 MR. M. KENNEDY: Mr. Brooks, can we have
02:20:07 7 PDX 5-6.

02:20:07 8 BY MR. M. KENNEDY:

02:20:08 9 Q Dr. Nicholson, what's depicted on this slide?

02:20:10 10 A This slide is showing between 2013 and 2018 the number of
02:20:15 11 Vascepa prescriptions that were filled, and what it shows is
02:20:20 12 that -- in thousands, so the vertical axis is in thousands.

02:20:24 13 So it shows Vascepa filled -- there are 174,000
02:20:29 14 prescriptions of Vascepa filled in 2013, and that increased up
02:20:33 15 to 1.3 million prescriptions in 2018 which is about a
02:20:38 16 50 percent average annual increase, so pretty substantial
02:20:42 17 increase over time.

02:20:42 18 Q Is that increase relevant to your commercial success
02:20:47 19 analysis?

02:20:48 20 A It is, because it's demonstrating that Vascepa is
02:20:51 21 providing value in the marketplace, and it's providing an
02:20:54 22 increasing amount of value over time.

02:20:56 23 It's important to note that the most comparable drug
02:21:01 24 to Vascepa in the sense that it has the same indication,
02:21:04 25 Lovaza, was on the market and had a generic version in 2014.

02:21:10 1 So the generic Lovaza is much less expensive than Vascepa, and
02:21:15 2 so this indicates that patients and health insurers are
02:21:19 3 willing to pay a premium for the features of Vascepa.

02:21:21 4 Q Where did you get the data that went into creating
02:21:27 5 PDX 5-6?

02:21:27 6 A These data come from a company called IQVIA.

02:21:32 7 Q And I think Mr. Hofmann mentioned IQVIA this morning, but
02:21:36 8 what is IQVIA?

02:21:37 9 A IQVIA is a company which collects data and also produces
02:21:41 10 reports for the pharmaceutical industry, and they obtain
02:21:45 11 information from the pharmacies that indicates what drug is
02:21:48 12 dispensed, and they aggregate that up nationally.

02:21:53 13 MR. M. KENNEDY: Your Honor, I would like to
02:21:54 14 offer PDX 5-6 as summary exhibit under FRE 1006.

02:22:02 15 MR. ROUNDS: No objection, Your Honor.

02:22:03 16 THE COURT: 5-6 is admitted.

02:22:07 17 MR. M. KENNEDY: And I'd also like to move the
02:22:08 18 underlying documents PX 644 and PX 659. However, I again
02:22:14 19 would request the opportunity to redact those exhibits before
02:22:17 20 they appear on the public docket.

02:22:20 21 MR. ROUNDS: No objection.

02:22:21 22 THE COURT: They're admitted.

02:22:21 23 (Plaintiffs' Exhibit 5-6, 644 and 659
02:22:21 received in evidence.)

02:22:25 24 MR. M. KENNEDY: Mr. Brooks, could we please
02:22:26 25 have PDX 5-7.

02:22:26 1 BY MR. M. KENNEDY:

02:22:31 2 Q And, Dr. Nicholson, what are you showing on this slide?

02:22:35 3 A This figure is depicting for the same six years, 2013
02:22:39 4 through 2018, the amount of net sales that Amarin collected
02:22:43 5 for selling Vascepa in millions of dollars on the vertical
02:22:49 6 axis.

02:22:50 7 So Amarin received \$26 million in net sales for
02:22:53 8 Vascepa in 2013, and that increased to \$228 million in 2018
02:23:00 9 which is a 54 percent average annual increase year over year.

02:23:05 10 Q Is that upward trend relevant to your commercial success
02:23:08 11 opinion?

02:23:08 12 A It is, because, as with prescriptions, it indicates that
02:23:12 13 this product is providing value in the market, and patients
02:23:15 14 and health insurers are willing to pay a premium for the
02:23:19 15 features of Vascepa.

02:23:20 16 Q Now, you use the term net sales. What do you mean by net
02:23:24 17 sales?

02:23:24 18 A Net sales are gross sales minus items such as any
02:23:29 19 returns, but, importantly, any co-pay cards or patient support
02:23:34 20 programs or any discounts or rebates that Amarin might be
02:23:38 21 offering to health insurers.

02:23:41 22 Q Now, you heard Mr. Hofmann's testimony this morning about
02:23:44 23 discounts, rebates, and so forth?

02:23:46 24 A Yes, I did.

02:23:47 25 Q Does your calculation of net sales back out all of those

02:23:51 1 discounts and rebates and other deductions from gross sales
02:23:57 2 that Mr. Hofmann discussed today?

02:23:59 3 A Yes. What's being depicted here is net sales, and so all
02:24:04 4 of those items have already been subtracted out before being
02:24:07 5 displayed on this figure.

02:24:08 6 Q Where did you get the information to make slide PDX 5-7?

02:24:14 7 A This figure was produced from a document internal to
02:24:18 8 Amarin. Amarin collected much of that information from --
02:24:21 9 from financial statements.

02:24:22 10 Q And, again, this graph only goes to 2018. It doesn't
02:24:26 11 reflect Amarin's sales for 2019 or 2020; is that right?

02:24:30 12 A Yes, that's right.

02:24:33 13 MR. M. KENNEDY: Your Honor, I would like to
02:24:34 14 offer PDX 5-7 as a summary exhibit under FRE 1006.

02:24:41 15 MR. ROUNDS: No objection, Your Honor.

02:24:43 16 MR. M. KENNEDY: And --

02:24:43 17 THE COURT: Go ahead.

02:24:44 18 MR. M. KENNEDY: And I would also like to offer
02:24:46 19 the underlying Exhibit PX 589 with the request that we be
02:24:50 20 permitted to review it for redactions.

02:24:53 21 MR. ROUNDS: No objection.

02:24:53 22 THE COURT: All right. Both requests are
02:24:55 23 granted.

02:24:55 24 (Plaintiffs' Exhibits 5-7 and 589
02:24:55 received in evidence.)

02:24:57 25 MR. M. KENNEDY: Mr. Brooks, could I have

02:24:59 1 DDX 8-21. This is one of Mr. Hofmann's slides.

02:24:59 2 BY MR. M. KENNEDY:

02:25:04 3 Q And I think I already covered a lot of this, but do you
02:25:07 4 agree with Mr. Hofmann's testimony that the commercial
02:25:11 5 performance of Vascepa has been driven by discounts, rebates,
02:25:16 6 and other incentives?

02:25:18 7 A I do disagree with that. In my opinion -- well, first of
02:25:23 8 all, as I said, I'm subtracting rebates and discounts out from
02:25:27 9 net sales both when I'm displaying the trend but also in the
02:25:31 10 net present value analysis that we'll show. So I've already
02:25:35 11 subtracted and accounted for discounts and rebates.

02:25:37 12 But discounts and rebates are quite common. It's
02:25:40 13 quite common for pharmaceutical firms to offer such discounts
02:25:44 14 and rebates to health insurers these days.

02:25:48 15 MR. M. KENNEDY: Mr. Brooks, can we have PX 746.

02:25:48 16 BY MR. M. KENNEDY:

02:25:53 17 Q Dr. Nicholson, do you recognize this document?

02:25:55 18 A I do.

02:25:55 19 Q What is it?

02:25:56 20 A This is a report that IQVIA, the company that we've
02:26:01 21 discussed before, produced in 2016 to look at the prevalence
02:26:06 22 and the magnitude of discounts and rebates that manufacturers,
02:26:10 23 pharmaceutical firms, were offering to part D health insurance
02:26:15 24 plans.

02:26:16 25 Q Just to define a couple terms, what is part D?

02:26:19 1 A Part D is the prescription drug benefit for Medi-Care
02:26:25 2 beneficiaries, so the elderly and some disabled.

02:26:28 3 Q What kind of role does Medi-Care part D play in the
02:26:31 4 overall healthcare economy?

02:26:33 5 A Medi-Care patients are important. The elderly tend to
02:26:37 6 use more medical services, including prescription drugs, than
02:26:40 7 the young.

02:26:40 8 But Medi-Care part D is administered by private
02:26:43 9 health insurers, the same -- generally the same private health
02:26:46 10 insurers that are offering insurance benefits to the non
02:26:51 11 elderly, the people who receive insurance through their
02:26:53 12 employer.

02:26:54 13 Q You mentioned IQVIA. Did IQVIA used to be known as
02:26:58 14 Quintiles IMS?

02:26:59 15 A Yes, that's correct.

02:27:00 16 Q Did you rely on PX 746 in forming your opinions in this
02:27:08 17 case?

02:27:08 18 A Yes, I did.

02:27:10 19 MR. M. KENNEDY: Your Honor, Amarin offers
02:27:13 20 PX 746 into evidence.

02:27:14 21 MR. ROUNDS: No objection, Your Honor.

02:27:14 22 THE COURT: 746 is admitted.

02:27:14 23 (Plaintiffs' Exhibit 746 received in
02:27:16 evidence.)

02:27:17 24 MR. M. KENNEDY: Mr. Brooks, can we go to page 5
02:27:20 25 of PX 746.

02:27:20 1 BY MR. M. KENNEDY:

02:27:23 2 Q And I would like to -- Dr. Nicholson, what does the graph
02:27:26 3 on this page show?

02:27:28 4 A What this shows, if you compare the green bar there in
02:27:33 5 the middle to the blue bar, what it shows is that
02:27:39 6 manufacturers on average in Medi-Care part D, pharmaceutical
02:27:45 7 firms, pharmaceutical firms are receiving on average 62
02:27:47 8 percent of the price.

02:27:48 9 In other words, they're giving discounts and rebates
02:27:51 10 on average of 38 percent to private health insurers.

02:27:55 11 So this is part of my opinion that discounts and
02:27:59 12 rebates are common and they sometimes are quite sizeable.

02:28:03 13 MR. M. KENNEDY: Mr. Brooks, could we go to
02:28:06 14 PDX 5-8.

02:28:06 15 BY MR. M. KENNEDY:

02:28:12 16 Q Dr. Nicholson, what does this slide show?

02:28:15 17 A This slide shows the determinants of the two comparison
02:28:22 18 groups that I formed for purposes of calculating Vascepa's
02:28:26 19 market share.

02:28:27 20 So I formed two comparison groups. I think the most
02:28:31 21 relevant comparison group for Vascepa would include the drugs
02:28:34 22 in the first two rows of this chart.

02:28:37 23 So, Vascepa and Lovaza are both indicated for
02:28:41 24 reducing TG levels amongst patients with very high TG, and
02:28:48 25 they are also both omega-3 fatty acids derivatives.

02:28:51 1 So one comparison group would consist of Vascepa,
02:28:54 2 Lovaza, and generic Lovaza, and I'll show market share of
02:28:58 3 Vascepa in that group.

02:29:00 4 I also consider a broader group of drugs that are
02:29:04 5 indicated to reduce TG levels, so that would include the drugs
02:29:08 6 that are on all five of the rows that are on this including
02:29:12 7 the fenofibrates, gemfibrozil and niacin.

02:29:18 8 Q Why is market share relevant to a commercial success
02:29:21 9 analysis?

02:29:21 10 A When you look at a drug's market share, you can see what
02:29:25 11 percentage of the patients are taking that drug versus other
02:29:29 12 drugs that ostensibly similar or potentially similar. You can
02:29:33 13 also see if that's trending up over time.

02:29:35 14 And as I mentioned, because all of the drugs that
02:29:38 15 are in this figure other than Vascepa have a generic version
02:29:42 16 on the market, if it's the case that Vascepa's market share is
02:29:47 17 growing over time then it means that it's capturing share from
02:29:51 18 less expensive products, in other words, the physicians, the
02:29:54 19 patients, and the health insurers are willing to prescribe or
02:29:57 20 pay for a higher priced drug Vascepa because of the features
02:30:02 21 that it has.

02:30:03 22 Q So generic drugs tend to be less expensive than branded
02:30:07 23 drugs?

02:30:07 24 A Yes, and usually quite a bit less expensive.

02:30:10 25 MR. M. KENNEDY: Mr. Brooks, can we have

02:30:12 1 PDX 5-9, please.

02:30:12 2 BY MR. M. KENNEDY:

02:30:16 3 Q And, Dr. Nicholson, what does this slide depict?

02:30:19 4 A This shows for 2013 through 2018 the market share of
02:30:25 5 Vascepa using those two different comparison groups that I
02:30:28 6 just described on the prior page.

02:30:31 7 So you're going to test my color. I think the
02:30:34 8 bluish green bar that's on the higher side, that would be the
02:30:37 9 market share of Vascepa in the omega-3 fatty acid comparison
02:30:42 10 group, the most relevant one in my opinion.

02:30:43 11 Q Perhaps we should have picked different colors for the
02:30:47 12 comparison.

02:30:49 13 Where did -- I'm sorry, go ahead.

02:30:49 14 A I was just going to say the share amongst the omega-3
02:30:54 15 fatty acids for Vascepa goes from four percent in 2013 up to
02:30:57 16 32 percent market share in 2018.

02:31:00 17 Q How does that impact your opinion on commercial success?

02:31:03 18 A This provides strong evidence that Vascepa is capturing
02:31:11 19 share from other drugs. It's pulling patients who otherwise
02:31:15 20 would take another product and instead they're deciding to
02:31:19 21 take Vascepa. So that's a strong indicator of value and of
02:31:23 22 increasing value over time.

02:31:25 23 Q And the products against whom Vascepa is competing tend
02:31:28 24 to be lower priced because they're generic; is that right?

02:31:32 25 A Yes, correct, both for the omega-3 fatty acid comparison

1 and for the lighter blue, which is the broader set of TG
2 reducing drugs where Vascepa's share rises over time to six
3 percent in that broader category in 2018.

4 Q And where did you get the data that went into this slide,
5 PDX 5-9?

6 A These data come from IQVIA.

7 MR. M. KENNEDY: Your Honor, Amarin offers
8 PDX 5-9 as a summary exhibit under FRE 1006.

9 MR. ROUNDS: No objection, Your Honor.

10 THE COURT: It's admitted.

11 (Plaintiffs' Exhibit 5-9 received in
12 evidence.)

13 MR. M. KENNEDY: And I think the underlying
14 documents have already been admitted, 644 and 659.

15 THE COURT: I believe so. It sounds familiar.
16 Yes, both are admitted.

17 MR. M. KENNEDY: Okay. Mr. Brooks, can we have
18 PDX 5-10, please.

19 BY MR. M. KENNEDY:

20 Q Dr. Nicholson, what you showing on this slide?

21 A Here I'm showing a little bit more detail on the market
22 share trend over time for the omega-3 fatty acid group.

23 So let me begin -- just reminding everyone, this is
24 the same years, 2013 through 2018. The vertical axis is
25 market share.

The blue line is showing the same data I showed

before, that Vascepa's market share in the omega-3 fatty acid category goes to four percent in 2013 to 32 percent in 2018.

What you can see with the orange line, that's branded Lovaza, so its market share goes from approximately 96 percent in 2013 and then it falls substantially when generic Lovaza enters in 2014, and currently branded Lovaza's market share is in the single digits, under five percent.

Q Is this typical of what happens when a generic substitute enters the market?

A It is. It's very common for 95 percent of the patients who were taking a branded drug to shift to the generic version or to other products.

Q And, Dr. Nicholson, did you create this slide based on the IQVIA data we've discussed earlier?

A Yes, I did.

MR. M. KENNEDY: Your Honor, Amarin would like to admit PDX 5-10 as a summary exhibit under FRE 1006.

MR. ROUNDS: No objection, Your Honor.

THE COURT: 5-10 is admitted.

(Plaintiffs' Exhibit 5-10 received in evidence.)

MR. M. KENNEDY: Mr. Brooks, can we have DDX 8-7. This is one of Mr. Hofmann's slides from this morning.

BY MR. M. KENNEDY:

Q And, Dr. Nicholson, were you in the courtroom when

02:34:10 1 Mr. Hofmann discussed this slide?

02:34:12 2 A Yes, I was.

02:34:13 3 Q And in particular when Mr. Hofmann discussed the
02:34:17 4 declining prescriptions for the TG lowering segment as a
02:34:21 5 whole?

02:34:21 6 A Yes.

02:34:23 7 Q Do you agree with his opinion that this slide shows that
02:34:27 8 Vascepa has not been performing well in the market?

02:34:31 9 A No. I have a very different interpretation of this. I
02:34:34 10 think if every single drug's prescriptions are decreasing, and
02:34:39 11 there's one that's bucking that trend and its prescriptions
02:34:43 12 are increasing, I think that speaks very highly of its
02:34:46 13 positive performance in the market.

02:34:48 14 Q And does Vascepa meet the description from your previous
02:34:51 15 answer?

02:34:52 16 A Yes. It's the only of these products whose prescriptions
02:34:56 17 are increasing, including in most recent years, generic
02:35:01 18 Lovaza's prescriptions are decreasing.

02:35:03 19 MR. M. KENNEDY: Mr. Brooks, can we have
02:35:08 20 DDX 8.8.

02:35:08 21 BY MR. M. KENNEDY:

02:35:08 22 Q So, Dr. Nicholson, did you see Mr. Hofmann present this
02:35:12 23 prescription share analysis this morning?

02:35:16 24 A Yes, I did.

02:35:16 25 Q Do you agree with Mr. Hofmann that this prescription

02:35:21 1 share analysis on DDX 8.8 shows that Vascepa has not performed
02:35:27 2 well commercially?

02:35:29 3 A I do disagree. I don't think this is the appropriate way
02:35:33 4 to look at market share in the pharmaceutical market where
02:35:37 5 it's very common for a new product on the market to experience
02:35:41 6 growing sales and growing market share over time as more
02:35:45 7 prescribers become aware of the products, more patients become
02:35:49 8 aware of it, and more prescribers become aware of the
02:35:52 9 attributes.

02:35:53 10 So, in my opinion, it's very important to look at
02:35:55 11 the lifecycle trend in market share which I've done in the
02:35:59 12 previous figures, to look at the initial and subsequent market
02:36:03 13 share, rather than collapsing it into a six-year figure as
02:36:06 14 Mr. Hofmann did.

02:36:07 15 Q So this figure that Mr. Hofmann gave is simply for the
02:36:10 16 entire six-year period from 2013 to 2018?

02:36:15 17 A That's correct, whereas the figures I showed are year by
02:36:19 18 year.

02:36:19 19 MR. M. KENNEDY: Mr. Brooks, can we have
02:36:23 20 PDX 5-11.

02:36:23 21 BY MR. M. KENNEDY:

02:36:26 22 Q And, Dr. Nicholson, you heard some discussion about your
02:36:28 23 Net Present Value analysis from Mr. Hofmann this morning. Do
02:36:33 24 you remember that testimony?

02:36:34 25 A Yes, I do.

Q So what is Net Present Value?

A Net Present Value is, by far, the most common method that businesses use, not just pharmaceutical firms, but all businesses use to try to determine whether to launch a new product, whether to launch a new service, whether to build a new factory.

And it's also a way for businesses to track whether a product or service is successful or not. At essentially a high level, what it consists of is for each year that a product is being developed around the market, you identify initially what the losses are, in the case of Vascepa, the losses associated with performing research and development and launching the drug, and then there's a series of years where the profits are positive either currently or expected to be positive.

So you identify the cash flows for every single year of the lifecycle of the drug. So it would be a series of negative losses and then a series of positive profits.

The second thing is to then acknowledge that investors, the investors who gave a company like Amarin the funds to develop the drug, are expecting a return. So you need to account for the return that they expect.

So if a project or a product has a Net Present Value of zero, that means it's going to precisely recoup the R&D costs so the investors will get their average return and no

02:38:11 1 more than that.

02:38:12 2 A project with a positive Net Present Value is one
02:38:16 3 that's delivering an above average return to investors for
02:38:21 4 similar products, products developed by small pharmaceutical
02:38:25 5 firms.

02:38:26 6 Q What's the significance when a net present value turns
02:38:28 7 from negative to positive?

02:38:30 8 A So when it goes from negative to positive, when it
02:38:35 9 becomes positive, it has recouped the R&D costs in the sense
02:38:40 10 of investors have received a return that's average for the
02:38:43 11 industry.

02:38:44 12 When it becomes positive, then they're receiving a
02:38:47 13 return that exceeds the average for similar products in the
02:38:51 14 industry.

02:38:52 15 Q So you heard Mr. Hofmann took issue with your decision to
02:38:56 16 use the net present value analysis to assess Vascepa's
02:38:59 17 commercial success in this case. Why do you think net present
02:39:03 18 value is the appropriate methodology here?

02:39:07 19 A It's what's used in this industry, and for good reason,
02:39:11 20 that pharmaceutical products have very long lives, patents run
02:39:15 21 for 20 years.

02:39:16 22 So when a company is considering developing a
02:39:19 23 product, they're looking at a series of very substantial
02:39:22 24 losses, in the case of Amarin, the 465 million of R&D that was
02:39:27 25 required.

02:39:28 1 Then they're going to be looking at the full set of
02:39:31 2 profits that they're going to obtain from that, not just over
02:39:35 3 the first six years, but over all the years at which they have
02:39:38 4 market exclusivity which generally in this industry is 10 to
02:39:44 5 15 years without a company like Amarin having to compete with
02:39:47 6 generics that are selling a bioequivalent version of the
02:39:51 7 product.

02:39:52 8 Q You've touched on this, but how do companies use Net
02:39:56 9 Present Value in the real world?

02:39:58 10 A Well, they do, I believe, what I'm doing which is to
02:40:01 11 consider the cash flows, and that's just really a way of
02:40:06 12 saying either losses or profits, the cash flows over the
02:40:09 13 entire period of time that product is expected to be viable in
02:40:15 14 the market, that is, not facing generic competition.

02:40:19 15 MR. M. KENNEDY: Mr. Brooks, can we have PX 602.
02:40:19 16 BY MR. M. KENNEDY:

02:40:26 17 Q Dr. Nicholson, do you recognize this document?

02:40:29 18 A This is the cover of a book called Principles of
02:40:34 19 Corporate Finance which is authored by Brealey and Myers.

02:40:39 20 Q And other than principles of corporate finance, can you
02:40:45 21 briefly explain what this book covers.

02:40:47 22 A This is a book I use in my healthcare finance class, and
02:40:51 23 I used it when I taught finance at Wharton. I think it's one
02:40:55 24 of the most common finance textbooks used in business programs
02:40:57 25 and graduate programs.

02:40:58 1 But it essentially teaches how companies make
02:41:03 2 investment decisions, and the Net Present Value method is
02:41:06 3 really at the core of this entire book.

02:41:08 4 Q Did you rely on PX 602 in forming your opinions in this
02:41:12 5 case?

02:41:13 6 A Yes, I did.

02:41:15 7 MR. M. KENNEDY: Your Honor, Amarin offers
02:41:18 8 PX 602 into evidence.

02:41:20 9 MR. ROUNDS: No objection.

02:41:21 10 THE COURT: Is PX 602 a copy of the book?

02:41:26 11 MR. M. KENNEDY: I believe it's a copy of a
02:41:28 12 chapter.

02:41:28 13 THE COURT: All right. PX 602 is admitted.

02:41:28 14 (Plaintiffs' Exhibit 602 received in
02:41:31 evidence.)

02:41:32 15 MR. M. KENNEDY: Mr. Brooks, may we have page 5
02:41:35 16 of PX 602.

02:41:35 17 BY MR. M. KENNEDY:

02:41:36 18 Q And, Dr. Nicholson, what is the topic of this chapter?

02:41:40 19 A This chapter, it's called Present Value and the
02:41:44 20 Opportunity Costs of Capital, but it's introducing to students
02:41:48 21 the Net Present Value model.

02:41:51 22 Opportunity costs of capital is another way of
02:41:53 23 explaining the investors' expected rate of return or the
02:41:57 24 discount rate that I mentioned in the prior slide.

02:42:00 25 MR. M. KENNEDY: Mr. Brooks, could we go to

02:42:02 1 page 10 and blow up the first full paragraph.

02:42:02 2 BY MR. M. KENNEDY:

02:42:08 3 Q And starting at the fifth line where it says "remember
02:42:12 4 this," Dr. Nicholson, what does this show about how NPV is
02:42:18 5 used?

02:42:20 6 A So what this is indicating is -- first, it's introducing
02:42:25 7 the notion of the discount rate or the opportunity costs of
02:42:29 8 capital. That's the investors' expected rate of return that
02:42:33 9 I've described earlier.

02:42:35 10 But it goes on to say,

02:42:36 11 "When you discount the project's expected
02:42:44 12 cash flow at its opportunity costs of capital, the
02:42:44 13 resulting present value is the amount investors would
02:42:48 14 be willing it pay for the project. Any time you find
02:42:52 15 and launch a positive NPV project, a project with
02:42:56 16 present value exceeding its required cash outlay, you
02:43:00 17 have made your company's stockholders better off."

02:43:03 18 So, in other words, it's basically outlining why
02:43:09 19 Net Present Value -- why companies pursuing positive Net
02:43:12 20 Present Value projects are providing higher than average
02:43:14 21 returns for their investors.

02:43:16 22 Q In what context have you personally use the Net Present
02:43:19 23 Value analysis?

02:43:21 24 A I teach it in my healthcare finance class, particularly
02:43:25 25 cases involving valuing drugs in development, and I've also

02:43:30 1 used it in my research as well.

02:43:32 2 MR. M. KENNEDY: Mr. Brooks, can we have PX 600.

02:43:32 3 BY MR. M. KENNEDY:

02:43:36 4 Q Dr. Nicholson, do you recognize that document?

02:43:41 5 A Yes, this is an article published in 2015 in a journal
02:43:46 6 called *Health Affairs* published by Ernie Berndt and
02:43:51 7 co-authors.

02:43:51 8 Q Is this a document you relied on in forming your opinions
02:43:55 9 in this case?

02:43:56 10 A Yes, it is.

02:43:56 11 MR. M. KENNEDY: Your Honor, we offer PX 600
02:43:59 12 into evidence.

02:44:02 13 MR. ROUNDS: NO objection, Your Honor.

02:44:03 14 I do wonder whether these are going to helpful
02:44:05 15 to the Court, and whether the Court is actually going to have
02:44:07 16 the opportunity to read these, but if they want to keep doing
02:44:10 17 this, no objection.

02:44:11 18 MR. M. KENNEDY: I mean, I will leave to the
02:44:13 19 Court what it helpful and not helpful. I wouldn't presume
02:44:17 20 opine on that.

02:44:19 21 THE COURT: PX 600 is admitted.

02:44:19 22 (Plaintiffs' Exhibit 600 received in
02:44:22 23 evidence.)

02:44:23 23 MR. M. KENNEDY: Dr. Nicholson can we move to --
02:44:24 24 or, Mr. Brooks, can we move to page 2.

02:44:24 25

02:44:24 1 BY MR. M. KENNEDY:

02:44:27 2 Q And I would like to ask you, starting at the seventh line
02:44:30 3 of the methods paragraph, what -- what concept is being
02:44:37 4 discussed here?

02:44:41 5 A So I think this will become clear shortly. One of the
02:44:45 6 things this article is doing is it's looking at drugs that
02:44:48 7 were launched in the U.S. between 2005 and 2009, and at the
02:44:52 8 time of the article, many of those drugs had not experienced
02:44:56 9 generic entry. They were still in their market exclusivity
02:45:01 10 period.

02:45:02 11 And so, as part of the methods, they're doing the
02:45:04 12 same thing that I do, and that is to calculate the lifetime
02:45:07 13 sales for drugs whose lifetime had not concluded, we modeled
02:45:13 14 subsequent sales applying different methods for small
02:45:16 15 molecules and biologics.

02:45:18 16 In other words, rather than looking, in Vascepa's
02:45:21 17 case, at just the first six years, what these authors do with
02:45:24 18 drugs that haven't experienced generic entry, is they forecast
02:45:28 19 sales up until generics are expected to enter.

02:45:33 20 MR. M. KENNEDY: Mr. Brooks, could we go to
02:45:35 21 page 5, and could we blow up Exhibit 3, the graph at the
02:45:38 22 bottom of the page.

02:45:38 23 BY MR. M. KENNEDY:

02:45:42 24 Q Dr. Nicholson, what's being shown here?

02:45:45 25 A I'll focus on the two vertical bars to the far right.

02:45:51 1 First of all, the title, I think, is useful in
02:45:54 2 indicating that the authors are also using the present value
02:45:58 3 method to look at whether drugs are recouping their R&D, but
02:46:03 4 what you can see here for 2005 to 2009 is, across all the
02:46:07 5 drugs that were launched in the U.S. in that five-year time
02:46:11 6 period, they're concluding that the average net present value
02:46:14 7 is going to be negative.

02:46:16 8 And you can see that because the bar all the way to
02:46:21 9 the right with the four segments, that's the present value of
02:46:24 10 the costs associated with those drugs, and it exceeds the
02:46:27 11 present value of the revenue.

02:46:29 12 So the difference would be negative, meaning across
02:46:31 13 that whole set of drugs, they're concluding the average Net
02:46:35 14 Present Value is negative.

02:46:36 15 Q So how does that feed into your overall opinion
02:46:41 16 concerning Vascepa?

02:46:42 17 A I think it supports my use of NPV, but I think it also --
02:46:45 18 as I'm going to show, Vascepa has a positive Net Present
02:46:49 19 Value, and I think here you can see that that's, at least for
02:46:51 20 recent drugs, again, bucking the trend. It's somewhat
02:46:56 21 unusual.

02:46:56 22 Some of these have positive NPV, but across all of
02:46:59 23 them it's negative, so Vascepa stands out in that sense.

02:47:02 24 MR. M. KENNEDY: Mr. Brooks, can we have
02:47:05 25 PDX 5-12, please.

02:47:05 1 BY MR. M. KENNEDY:

02:47:08 2 Q And, Dr. Nicholson, what -- could you explain the
02:47:12 3 elements you considered in forming your NPV analysis for
02:47:17 4 Vascepa.

02:47:18 5 A Yes. So I began with the actual research and development
02:47:23 6 spending that Amarin incurred for -- to develop Vascepa. So
02:47:27 7 those are actual R&D costs over this 11-year time period.

02:47:32 8 I then incorporated the actual sales from 2013
02:47:37 9 through 2018, and then as just referenced, because Vascepa's
02:47:44 10 lifecycle is not done, there's still market exclusivity
02:47:48 11 remaining, I used five analysts' reports to form an average
02:47:54 12 forecasted sales for Vascepa from 2019 through 2029.

02:48:01 13 Q A couple of follow-up questions. Why do you assume
02:48:04 14 generic entry in August 2029?

02:48:09 15 A So as indicated in the second to bottom row, according to
02:48:13 16 a publically announced settlement agreement, I'm assuming that
02:48:19 17 Teva will enter with a generic product in August of 2029, and
02:48:23 18 then I conservatively assumed that Vascepa's sales will be
02:48:27 19 zero after that generic entry.

02:48:28 20 Q What's a discount rate?

02:48:29 21 A So the discount rate here of 8.6 percent is the
02:48:35 22 investors' expected rate of return for investing in small
02:48:40 23 pharmaceutical firms, or it's the cost of capital, or it's the
02:48:43 24 discount rate. Those three are really interchangeable.

02:48:47 25 MR. M. KENNEDY: Mr. Brooks could we have

02:48:49 1 PDX 5-13.

02:48:49 2 BY MR. M. KENNEDY:

02:48:52 3 Q Dr. Nicholson, so what does this slide show?

02:48:55 4 A So this shows from 2018 to 2029 on the horizontal axis,
02:49:02 5 either actual sales or forecasted sales in millions of dollars
02:49:06 6 for Vascepa.

02:49:07 7 So if you begin all the way in the left with 2018,
02:49:10 8 that's an actual \$228 million of sales that Amarin collected
02:49:15 9 for Vascepa.

02:49:17 10 Then in 2019, it's kind of hard to see, but there's
02:49:21 11 five different sales forecasts that were provided by the five
02:49:26 12 Wall Street analysts whose reports are indicated in the upper
02:49:30 13 left of this figure.

02:49:34 14 Let me just take -- say that the green line on the
02:49:37 15 bottom, the Cantor analyst, the solid line would be years when
02:49:43 16 that particular analyst provided a specific sales forecast
02:49:49 17 estimate for Vascepa for that year.

02:49:51 18 So you can see that that analyst forecasted Vascepa
02:49:55 19 sales through 2027 and forecasted that those would be growing
02:50:00 20 year after year.

02:50:02 21 Likewise you can see the H.C. Wainwright analyst
02:50:04 22 forecast sales through 2028, the solid line.

02:50:09 23 Then the orange line in the middle, you can see
02:50:12 24 SunTrust, that analyst forecasts sales through 2022.

02:50:16 25 Q So all these analyst reports, am I correct, they date

02:50:20 1 from early 2019?

02:50:21 2 A Yes, it would be between January 6th and late February of
02:50:25 3 2019.

02:50:26 4 Q And am I correct that these are the latest reports you
02:50:28 5 had available when you prepared your expert report?

02:50:31 6 A That's correct. These were reports where the analyst had
02:50:35 7 forecasted Vascepa sales and operating margins by reputable
02:50:41 8 firms, and I collected all five of them.

02:50:43 9 Q So am I correct these numbers don't reflect more recent
02:50:47 10 Amarin actual sales, nor do they reflect approval of the
02:50:50 11 REDUCE-IT indication?

02:50:51 12 A That's correct.

02:50:53 13 Q And how would the -- how would the December 19 approval
02:50:57 14 of the REDUCE-IT indication affect the forecast just at a high
02:51:01 15 level?

02:51:01 16 MR. ROUNDS: Your Honor, I'm going to object to
02:51:03 17 that, that's beyond the scope of the report.

02:51:06 18 MR. M. KENNEDY: Well, I think Mr. Hofmann got
02:51:08 19 into the effect of the REDUCE-IT indication.

02:51:10 20 I'm not asking for a detailed update to the
02:51:13 21 analysis, just directionally would having the approval
02:51:17 22 granted, you know, affect his analysis positively or
02:51:22 23 negatively. I think that's in line with what Mr. Hofmann
02:51:24 24 testified this morning.

02:51:25 25 THE COURT: Mr. Rounds?

02:51:26 1 MR. ROUNDS: Yeah, Your Honor, I think he's
02:51:28 2 trying to corroborate numbers that he has in his report with
02:51:30 3 information that we have not had access to and that we can't
02:51:34 4 cross-examine. It's improper.

02:51:35 5 THE COURT: Well, Mr. Hofmann, did he testify --
02:51:37 6 I thought it was on cross-examination that the REDUCE-IT
02:51:41 7 indication would affect it one direction. Is that what you're
02:51:45 8 getting at, Mr. Kennedy?

02:51:47 9 MR. M. KENNEDY: Partly, but also on direct he
02:51:49 10 brought up the REDUCE-IT indication and -- as a way to dismiss
02:51:52 11 its importance on his view that there's no nexus, but he did
02:51:56 12 testify substantively about it.

02:51:58 13 And I'm not going to get into numbers that are
02:52:01 14 postdating his expert report, all I was trying to elicit is
02:52:06 15 just as a general matter, an approval that was pending at the
02:52:10 16 time of Dr. Nicholson's opinions, now it's not pending
02:52:13 17 anymore, is that good or bad for the certainty of the
02:52:16 18 certainty of the analysts' assessments.

02:52:17 19 I think at that high level, that's fair given
02:52:20 20 the testimony today.

02:52:21 21 THE COURT: But it does exceed the scope of his
02:52:23 22 report.

02:52:24 23 MR. M. KENNEDY: Well, that's correct --

02:52:25 24 THE COURT: Because at the time he testified,
02:52:26 25 Amarin was going through the approval process, but he wasn't

asked if the REDUCE-IT indication was approved, what would happen.

MR. M. KENNEDY: That's correct.

THE COURT: The objection is overruled, and I think the answer is obvious as well. The objection -- I'm sorry, the objection is sustained, otherwise I would say that I think the answer is obvious.

MR. M. KENNEDY: Thank you. I'll move on, Your Honor.

BY MR. M. KENNEDY:

Q So I think you just mentioned this, but what is your view of the reputation in the marketplace of the five analysts' reports you reviewed?

A In my opinion, these are reputable firms, and, as Mr. Hofmann said, they're using all of the information available to them to make the most accurate estimates possible.

And I would just go on to add that, you know, the information that analysts provided in general is often pivotal for directing millions if not billions of dollars of investments. So these analysts' reports are generated with care, and they try to be as accurate as possible.

Q What's the benefit of using all five of these reports?

A Well, the benefit is you get a more accurate forecast.

If you have one analyst that is slightly

02:53:40 1 overestimating in ex post, overestimating in Vascepa sales,
02:53:46 2 that's going to be then offset with an analyst who might be
02:53:51 3 subtly underestimating.

02:53:51 4 So by having multiple, in this case five, you
02:53:53 5 increase the precision of the forecast.

02:53:56 6 And if I can just say, I just want to make sure I
02:53:58 7 explain the dotted lines just in case that's not obvious.

02:54:04 8 Not all of the analysts forecast sales of Vascepa
02:54:06 9 all the way through the projected end of market exclusivity.
02:54:12 10 The dotted lines would be my linear extrapolations which I
02:54:16 11 believe is conservative because whenever the analysts are
02:54:21 12 reporting specific sales figures, you can see that they're
02:54:24 13 increasing.

02:54:25 14 So I'm linearly increasing those, and it's
02:54:28 15 conservative because it implies a decreasing growth rate in
02:54:33 16 the sales over time.

02:54:34 17 Q Are the analysts' reports relied on informing your NPV
02:54:39 18 analysis cited at the bottom of PDX 5-13?

02:54:43 19 A Yes, they are.

02:54:44 20 MR. M. KENNEDY: Your Honor, we would like to
02:54:45 21 offer PDX 5-13 as a summary exhibit under FRE 1006.

02:54:51 22 MR. ROUNDS: No objection.

02:54:52 23 THE COURT: 5-13 is admitted.

02:54:52 24 (Plaintiffs' Exhibit 5-13 received in
02:54:55 evidence.)

02:54:55 25 MR. M. KENNEDY: And we'd also like to admit the

02:54:57 1 underlying analysts' reports which listed on the slide,
02:55:06 2 PX 657, PX 658, PX 661, PX 663 and PX 711.

02:55:16 3 THE COURT: Any objection, Mr. Rounds?

02:55:18 4 MR. ROUNDS: None, Your Honor.

02:55:20 5 THE COURT: The underlying five analysts'
02:55:22 6 reports are also admitted.

02:55:02 7 (Plaintiffs' Exhibits 590, 657, 658, 661,
02:55:13 663 and 711 received in evidence.)

02:55:25 8 THE COURT: Miss Clerk, do you need that to be
02:55:26 9 read again?

02:55:27 10 THE CLERK: No.

02:55:28 11 THE COURT: Okay. Thank you.

02:55:34 12 Would this be a good time for us to take our
02:55:36 13 afternoon recess, or are you almost --

02:55:39 14 MR. M. KENNEDY: We probably should.

02:55:40 15 THE COURT: All right. We'll take our afternoon
02:55:42 16 recess.

02:55:42 17 (A recess was taken.)

03:18:01 18 THE COURT: Please be seated.

03:18:08 19 MR. M. KENNEDY: Your Honor, may I proceed?

03:18:10 20 THE COURT: Yes.

03:18:11 21 MR. M. KENNEDY: Mr. Brooks, let's have
03:18:13 22 PDX 5-42, please.

03:18:13 23 BY MR. M. KENNEDY:

03:18:17 24 Q Dr. Nicholson, what are you showing on this slide?

03:18:19 25 A So this shows the same years that were on the prior

03:18:22 1 slide. The prior slide looked at actual sales and forecasted
03:18:26 2 sales from the five analysts' reports.

03:18:28 3 Here, what I'm showing is the actual profit margin
03:18:32 4 of Vascepa, and then forecasted profit margin of Vascepa from
03:18:39 5 2018 through 2029.

03:18:41 6 Q How does the profit margin relate to your NPV analysis?

03:18:45 7 A It's an important input into the analysis because the
03:18:49 8 profit margin indicates what is the profit to Amarin after all
03:18:52 9 expenses.

03:18:53 10 So it would be revenues or sales, minus production
03:18:58 11 costs, minus R&D, minus selling general and administrative
03:19:02 12 costs, and then divided by sales. So, it's the profit as a
03:19:05 13 percentage of sales.

03:19:06 14 Q As of February 19, what was the consensus between these
03:19:10 15 five analysts as to when Amarin would become profitable?

03:19:15 16 A So, all five of the analysts forecasted that in 2020
03:19:19 17 Vascepa would be profitable. So all five of those dots are
03:19:23 18 above the zero percent horizontal line.

03:19:26 19 And then it's the same pattern here, the solid lines
03:19:30 20 indicate years when an analyst provided a specific operating
03:19:35 21 margin forecast.

03:19:36 22 The dotted lines would be where I very
03:19:39 23 conservatively assumed that the operating margin for that
03:19:42 24 analyst remained constant over the forecast window.

03:19:46 25 Q Why did you make that assumption?

03:19:50 1 A Well, I wanted to be conservative, and the reason it's
03:19:54 2 conservative is that all of the operating margins were
03:19:57 3 forecast to increase over the period where the analysts were
03:20:01 4 providing specific figures.

03:20:02 5 So you can see, for example, the Cantor analyst is
03:20:07 6 predicting rising operating margins all the way through 2027,
03:20:12 7 generally as the marketing expenditures start to decrease and
03:20:17 8 the R&D costs are no longer there.

03:20:18 9 So rather than assuming that when an analyst didn't
03:20:23 10 provide a forecast, rather than assuming it would rise, I very
03:20:27 11 conservatively assumed that it would just stay at that
03:20:30 12 constant level.

03:20:31 13 Q And to prepare PDX 5-14, you used the same analyst
03:20:36 14 reports that we looked at on the previous slide?

03:20:38 15 A That's correct, the same five reports.

03:20:41 16 MR. M. KENNEDY: Your Honor, we offer PX 5-14 as
03:20:43 17 a summary exhibit under FRE 1006.

03:20:48 18 MR. ROUNDS: No objection.

03:20:49 19 THE COURT: 5-14 is admitted.

03:20:49 20 (Plaintiffs' Exhibit 5-14 received in
03:20:49 21 evidence.)

03:20:52 21 MR. M. KENNEDY: Mr. Brooks, let's have
03:20:55 22 PDX 5-15.

03:20:55 23 BY MR. M. KENNEDY:

03:20:56 24 Q Dr. Nicholson, what are you showing on this slide?

03:21:00 25 A Here, I'm showing over Vascepa's entire lifecycle the

discounted cash flow year-by-year. So, again, cash flow is either going to be a loss when costs are greater than revenue, so everything from 2008 through 2019, and then it will be a positive profit from 2020 through 2029.

And I should just note that I'm taking an average of the profit across those five analysts' reports for 2019 through 2020.

So this is the year-by-year profit or loss already discounted, meaning already taking into account the expected return that investors would have for giving a company like Amarin funds to develop a drug.

Q And what is discounted cash flow?

A So it's, it's a way of putting each year of profit or loss on equal footing. It's to acknowledge that investors would give money to a company such as Amarin with an expectation that they would get a return on that. So, it takes future values and it reduced them to account for that.

Q And, again, you're relying on the same analysts' reports we've already looked at on other slides?

A Yes, that's correct.

MR. M. KENNEDY: Your Honor, we offer PDX 5-15 as summary exhibit under FRE 1006.

MR. ROUNDS: No objection, Your Honor.

THE COURT: 5-15 is admitted.

(Plaintiffs' Exhibit 5-15 received in evidence.)

MR. M. KENNEDY: Mr. Brooks, can we have

PDX 5-16.

BY MR. M. KENNEDY:

Q And, Dr. Nicholson, what are you showing here?

A So this is a cumulative version of the prior figure.

So the prior figure showed the year-by-year losses or profits for Vascepa. This is now accumulating those year after year, so just add the -- that cash flow to the prior year's cash flows.

And what this shows is, as Amarin's incurring losses when they're developing and launching Vascepa, the cumulative NPV line is getting more and more negative, and then it begins to turn upward in 2020 when the profits are forecast to be positive.

And then the NPV line intersects the X axis in 2024. So that indicates that I'm forecasting that Vascepa's Net Present Value will be zero in 2024. In other words, that's the year when investors will have recouped their investment and received the average return, the 8.6 percent return.

Thereafter, the NPV continues to increase up to 1.7 billion in 2028, and then 1.9 billion in 2029.

Q So 1.9 billion is the dot with 2029 that we didn't put a legend on?

A That's right. And that indicates that over its entire

03:23:57 1 lifecycle, Vascepa is expected to have a positive Net Present
03:24:01 2 Value at 1.9 billion or, in other words, deliver a return to
03:24:05 3 investors that exceeds the average return for the industry by
03:24:09 4 \$1.9 billion.

03:24:11 5 Q And what does this analysis tell you about whether
03:24:13 6 Vascepa is a commercial success?

03:24:16 7 A This indicates that Vascepa is a commercial success.
03:24:20 8 It's delivering above average returns to investors in the
03:24:23 9 industry.

03:24:25 10 Q And, again, you relied on the same analysts' reports and
03:24:28 11 financial information as with the previous few slides?

03:24:32 12 A Yes, that's correct.

03:24:34 13 MR. M. KENNEDY: Your Honor, we offer PDX 5-16
03:24:38 14 as a summary exhibit under FRE 1006.

03:24:42 15 MR. ROUNDS: No objection, Your Honor.

03:24:43 16 THE COURT: 5-16 is admitted.

03:24:43 17 (Plaintiffs' Exhibit 5-16 received in
03:24:43 18 evidence.)

03:24:46 18 MR. M. KENNEDY: Mr. Brooks, can we have

03:24:49 19 DDX 8.9.

03:24:49 20 BY MR. M. KENNEDY:

03:24:49 21 Q Dr. Nicholson, were you in the courtroom this morning
03:24:52 22 when Mr. Hofmann discussed some of the H.C. Wainwright
03:24:55 23 projections?

03:24:56 24 A Yes, I was.

03:24:57 25 Q What is your understanding of the point

03:24:59 1 Mr. Hofmann was trying to make with this particular slide?

03:25:03 2 A Well, my understanding is that Mr. Hofmann identified one
03:25:09 3 year, 2018, where one of the analysts overestimated the sales
03:25:15 4 that Vascepa actually collected for 2018.

03:25:18 5 So in 2015, '16, '17, when forecasting for the same
03:25:23 6 year 2018, one of the analysts of the five that I'm using
03:25:28 7 estimated sales that ended up being higher than what were
03:25:31 8 actually realized.

03:25:34 9 Q So do you agree with Mr. Hofmann that this calls into
03:25:37 10 question whether you should have relied on H.C. Wainwright as
03:25:41 11 part of your analysis?

03:25:43 12 A No. This, to me, reinforces the importance of using all
03:25:46 13 of the analysts' reports that were available that were
03:25:49 14 providing the forecasts that I needed.

03:25:51 15 It's what you would expect. Sometimes an analyst
03:25:54 16 making a forecast will make a prediction that's quite accurate
03:25:59 17 in retrospect, sometimes a little high, sometimes a little
03:26:04 18 low. But by including all five of the analysts' reports, and
03:26:06 19 taking an average, you have the opportunity to have a forecast
03:26:10 20 that's overly optimistic, offsetting one that might be overly
03:26:17 21 pessimistic.

03:26:18 22 MR. M. KENNEDY: Mr. Brooks, can we have
03:26:20 23 PDX 5-17.

03:26:20 24 BY MR. M. KENNEDY:

03:26:21 25 Q Dr. Nicholson, what are you showing on this slide?

03:26:24 1 A What I show here is that if you look at a couple of other
03:26:28 2 instances, it's the case that H.C. WainWright was forecasting
03:26:32 3 sales that ended up being too low. The Vascepa sales exceeded
03:26:36 4 what the H.C. WainWright analysts predicted.

03:26:40 5 So on the left, in early 2017, the H.C. WainWright
03:26:45 6 analysts forecast that for the full calendar year 2017, they
03:26:49 7 forecast Vascepa sales of 165.5 million. If you look on the
03:26:55 8 right, that's the actual 2017 sales for Vascepa,
03:27:01 9 179.8 million.

03:27:01 10 So this is an instance where H.C. WainWright was too
03:27:06 11 low in forecasting, and not too high.

03:27:09 12 And at the bottom, you can see something similar.
03:27:12 13 The analyst WainWright was forecasting operating losses of
03:27:18 14 46.6 million, and the losses ended up being smaller, less
03:27:23 15 negative than what the analyst forecast.

03:27:25 16 Q And at the bottom of this slide, you cite the H.C.
03:27:29 17 WainWright analysis for March 1st, 2017, and that's PX 752?

03:27:35 18 A Yes, that's correct.

03:27:36 19 Q Is that a document you relied on in forming your opinions
03:27:39 20 in this case?

03:27:40 21 A Yes.

03:27:42 22 MR. M. KENNEDY: Your Honor, we would like to
03:27:43 23 enter PX 752 into evidence.

03:27:46 24 THE COURT: Any objection?

03:27:48 25 MR. ROUNDS: No objection, Your Honor.

03:27:49 1 THE COURT: PX 752 is admitted.

03:27:49 2 (Plaintiffs' Exhibit 752 received in
03:27:49 evidence.)

03:27:49 3 BY MR. M. KENNEDY:

03:27:53 4 Q And, Dr. Nicholson, you compared that H.C. WainWright
03:27:56 5 projection from that year to Amarin's 10-K for fiscal year
03:27:58 6 ending December 31st, 2017, PX 637. Is that a document you
03:28:03 7 relied on in forming your opinions in this case?

03:28:06 8 A Yes.

03:28:07 9 MR. M. KENNEDY: Your Honor, Amarin moves to
03:28:09 10 admit PX 637.

03:28:14 11 MR. ROUNDS: No objection.

03:28:14 12 THE COURT: 637 is also admitted.

03:28:14 13 (Plaintiffs' Exhibit 637 received in
03:28:14 evidence.)

03:28:18 14 MR. M. KENNEDY: And, Mr. Brooks, can we go to
03:28:21 15 PDX 5-18, please.

03:28:21 16 BY MR. M. KENNEDY:

03:28:23 17 Q Dr. Nicholson, what does this slide show?

03:28:25 18 A This is another instance where H.C. WainWright
03:28:31 19 underestimated the actual sales for Vascepa, so, contrary to
03:28:34 20 the example that Mr. Hofmann provided this morning.

03:28:38 21 Specifically, on the left, you can see that in the
03:28:41 22 first quarter 2019 -- this is from the same analysts' report
03:28:44 23 that I used in the Net Present Value analysis -- the H.C.
03:28:48 24 WainWright analysts were forecasting that for the first
03:28:51 25 quarter, once it completed, the Vascepa would have sales of

03:28:55 1 65.7 million.

03:28:57 2 If you look at the right, from the financial
03:28:59 3 statement, Vascepa ended up having 72.7 million of sales. So
03:29:04 4 this is an instance where H.C. WainWright was too pessimistic.
03:29:09 5 They under-forecast the sales.

03:29:11 6 And at the bottom you can see something similar, in
03:29:14 7 the directional sense. The analysts were forecasting
03:29:17 8 operating losses for Amarin of 47.6 million for the first
03:29:22 9 quarter 2019. In the bottom right, you can see it ended up
03:29:27 10 being about half of that, so a much smaller loss in reality
03:29:31 11 than what was forecast.

03:29:32 12 Q The citation at the bottom of this slide, the H.C.
03:29:36 13 WainWright report from February 2019 is PX 658. Did you rely
03:29:41 14 on that analyst's report in forming your opinions in this
03:29:43 15 case?

03:29:44 16 A Yes.

03:29:45 17 MR. M. KENNEDY: Your Honor, we would like to
03:29:47 18 offer PX 658 into evidence.

03:29:50 19 MR. ROUNDS: No objection.

03:29:51 20 THE COURT: 658 is admitted.

03:29:54 21 BY MR. M. KENNEDY:

03:29:54 22 Q And you compared that projection to Amarin's 10-Q for
03:29:59 23 quarterly period ending March 31st, 2019, and that's PX 724.
03:30:02 24 Did you rely on that 10-Q in forming your opinions in this
03:30:06 25 case?

03:30:06 1 A Yes.

03:30:07 2 MR. M. KENNEDY: Amarin would like to move
03:30:11 3 PX 724 into evidence.

03:30:12 4 MR. ROUNDS: No objection.

03:30:12 5 THE COURT: 724 is admitted.

03:30:12 6 (Plaintiffs' Exhibit 724 received in
03:30:12 evidence.)

03:30:12 7 BY MR. M. KENNEDY:

03:30:15 8 Q So, Dr. Nicholson, I assume you heard that
03:30:18 9 Mr. Hofmann took issue with how you did your Net Present Value
03:30:23 10 calculation, and particularly your inclusion of the WainWright
03:30:27 11 analysis. Do you remember that testimony?

03:30:27 12 A Yes.

03:30:28 13 MR. M. KENNEDY: Mr. Brooks, let's have DDX 810.

03:30:28 14 BY MR. M. KENNEDY:

03:30:35 15 Q And, Dr. Nicholson, do you understand the point
03:30:37 16 Mr. Hofmann was trying to make this morning with this slide?

03:30:41 17 A I think so.

03:30:42 18 Q What is your understanding of his argument?

03:30:44 19 A Well, my understanding is that his conclusion was that
03:30:50 20 because in one of those instances H.C. WainWright
03:30:54 21 overestimated what Vascepa's actual sales were, that that was
03:30:58 22 reason to remove that analyst report from the Net Present
03:31:03 23 Value.

03:31:03 24 I just showed two instances where WainWright
03:31:06 25 underestimated sales, and so I strongly believe that all five

analyst reports should be included because that increases the accuracy of the Net Present Value analysis.

Q Well, let's say we did exclude the H.C. WainWright report, would that change your opinion as to whether Vascepa is a commercial success?

A No, and I don't think it's appropriate to omit H.C. WainWright. But even if one were to do that, Vascepa would still have a positive Net Present Value. It would be smaller than the one that I believe is appropriate, but I would still conclude that Vascepa is a commercial success.

MR. M. KENNEDY: Can we have PX 607.

BY MR. M. KENNEDY:

Q And, Dr. Nicholson, do you recognize that document?

A Yes. This is a title page of a book that I co-edited in 2012. It's called *The Economics of the Biopharmaceutical Industry*.

Q Is this a document you relied on in forming your opinions in this case?

A Yes.

MR. M. KENNEDY: Your Honor, we offer PX 607. I believe it's a chapter from this book.

MR. ROUNDS: Your Honor, I think we require a little more foundation to show that this is a learned treatise within the industry, just to pass the hearsay objection.

MR. M. KENNEDY: Sure.

03:32:25 1 BY MR. M. KENNEDY:

03:32:26 2 Q Dr. Nicholson, who edited *The Economics of the*
03:32:28 3 *Biopharmaceutical Industry*?

03:32:30 4 A I edited it along with my former colleague, Patricia
03:32:35 5 Danzon at the Wharton School of Penn. The Oxford publishers
03:32:40 6 approached us and asked us if we would be willing to assemble
03:32:44 7 a group of academics to publish a study on economics of the
03:32:49 8 industry.

03:32:49 9 Q And do you consider yourself an expert in the economics
03:32:51 10 of the biopharmaceutical industry?

03:32:55 11 A I do.

03:32:55 12 Q Is Ms. Danzon an expert in the economics of the
03:32:59 13 biopharmaceutical industry?

03:32:59 14 A She is, in my opinion, yes.

03:33:03 15 Q I don't want you to be immodest, but is this book used in
03:33:07 16 the field to teach about the economics of the
03:33:09 17 biopharmaceutical industry?

03:33:12 18 A I believe it is. I don't keep track, but I believe it
03:33:15 19 is, yes.

03:33:15 20 Q Generally, what kinds of topics are covered in this
03:33:19 21 handbook?

03:33:20 22 A This book was intending to really span the major issues
03:33:26 23 that biotech and pharmaceutical firms face over the course of
03:33:31 24 their -- the lifecycle of a drug.

03:33:33 25 So it looked as things such as patents, and where

03:33:36 1 companies raise their research and development money, how they
03:33:40 2 price their products, the role of marketing, mergers and
03:33:45 3 acquisitions, and licensing deals.

03:33:47 4 So it really tried to span both issues that come up
03:33:50 5 before a drug gets approved, and then also issues about
03:33:55 6 managing a drug once it's on the market.

03:33:57 7 Q Why is this handbook relevant to your opinions today?

03:34:02 8 A Well, this contains some -- it summarizes and describes
03:34:08 9 some of the studies that I think are pivotal in terms of
03:34:12 10 understanding the economics of the industry.

03:34:16 11 And, in particular, you know, how do academics treat
03:34:21 12 the lifecycle of a pharmaceutical product, or how often are
03:34:26 13 drugs actually commercially successful, how often do they
03:34:29 14 actually have a positive Net Present Value, things that are
03:34:33 15 important when companies decide whether or not to pursue
03:34:36 16 projects.

03:34:37 17 MR. M. KENNEDY: Your Honor, Amarin offers
03:34:40 18 PX 607 into evidence.

03:34:41 19 MR. ROUNDS: Same objection, Your Honor.
03:34:43 20 There's no evidence about how widely circulated, how widely
03:34:46 21 read, how widely used this is in the industry.

03:34:50 22 We maintain the objection.

03:34:51 23 MR. M. KENNEDY: I would just note this was
03:34:53 24 disclosed to defendants two days ago, and this is an objection
03:34:56 25 they could have raised in advance.

03:34:57 1 But, in any event, I believe I've laid adequate
03:35:00 2 foundation with an expert in the field on those topics.

03:35:03 3 THE COURT: I agree. And, Mr. Nicholson,
03:35:08 4 testified that he relied on the information in this chapter as
03:35:14 5 well in his report. I'm going to overrule the objection, and
03:35:18 6 we'll admit Exhibit 607.

03:35:18 7 (Plaintiffs' Exhibit 607 received in
03:35:18 evidence.)

03:35:24 8 MR. M. KENNEDY: Mr. Brooks, let's have page 20
03:35:28 9 of PX 607.

03:35:28 10 BY MR. M. KENNEDY:

03:35:29 11 Q And with reference to the graph on the top half of this
03:35:32 12 page, in your view, why is it appropriate to look at the
03:35:36 13 entire lifecycle of a drug in analyzing commercial success?

03:35:39 14 A Because drugs have very long lifecycles. They generally
03:35:47 15 exhibit a period of extended growth of sales once they reach
03:35:51 16 the market because it takes a while for physicians and
03:35:54 17 patients to become aware of a drug and to understand the
03:35:58 18 attributes of the drug.

03:35:59 19 If you look at the top figure, that's the sales
03:36:03 20 profile for the highest selling drugs that were launched in
03:36:10 21 the U.S. between 1990 and 1994, and what you can see is that
03:36:14 22 line increases for about 12 years. In other words, the sales
03:36:17 23 of the drugs continue increasing over an extended period.

03:36:21 24 So if one were to just truncate this at six years,
03:36:24 25 you would miss a lot of the important and higher sales period

03:36:29 1 of a drug's life.

03:36:30 2 Q Is this how the pharmaceutical industry, in general,
03:36:35 3 looks at these matters?

03:36:37 4 A Yes, it is.

03:36:37 5 MR. M. KENNEDY: Mr. Brooks, can we have PX 612.
03:36:37 6 BY MR. M. KENNEDY:

03:36:43 7 Q Now, Dr. Nicholson, what is this document?

03:36:45 8 A This is an article in a journal called *Nature Reviews*
03:36:52 9 *Drug Discovery* published in 2008 by Henry Grabowski.

03:36:57 10 Q And did you rely on this document in forming your
03:36:59 11 opinions in this case?

03:37:00 12 A I did.

03:37:04 13 MR. M. KENNEDY: Your Honor, we offer PX 612
03:37:05 14 into evidence.

03:37:07 15 MR. ROUNDS: No objection, Your Honor.

03:37:08 16 THE COURT: 612 is admitted.

03:37:08 17 (Plaintiffs' Exhibit 612 received in
03:37:08 evidence.)

03:37:10 18 MR. M. KENNEDY: Mr. Brooks, let's have page 6.
03:37:10 19 BY MR. M. KENNEDY:

03:37:13 20 Q And with reference to Figure 3, what is Figure 3 showing?

03:37:17 21 A So Figure 3 shows that, on average, when Henry Grabowski
03:37:26 22 looked at drugs that launched in the U.S. between 1980 and
03:37:30 23 1984, on average, it took those drugs 16 years to reach Net
03:37:35 24 Present Value of zero.

03:37:36 25 And what he's showing is the R&D costs as that

03:37:40 1 horizontal purple line, and then the present value of cash
03:37:45 2 flows, or profits, year by year. So it's more evidence that
03:37:50 3 present value was commonly used.

03:37:52 4 But, importantly, in my analysis, I'm estimating
03:37:56 5 that Vascepa's Net Present Value will turn positive in its
03:38:00 6 twelfth year in market, and that will be four years faster
03:38:04 7 than average, according to this study.

03:38:06 8 MR. M. KENNEDY: Let's turn to the nexus
03:38:08 9 analysis. Mr. Brooks, let's have PDX 5-19.

03:38:08 10 BY MR. M. KENNEDY:

03:38:13 11 Q And, Dr. Nicholson, how did you go about performing your
03:38:17 12 nexus analysis?

03:38:19 13 A So I first looked at whether there was any evidence that
03:38:25 14 the commercial success of Vascepa was being driven by factors
03:38:29 15 other than the patented features in a substantial way,
03:38:33 16 specifically was it the case that Amarin was marketing or
03:38:37 17 promoting Vascepa more than average in the industry, and,
03:38:42 18 also, what was the nature of the marketing, so what were the
03:38:45 19 messages or the features that were being featured in the
03:38:48 20 marketing.

03:38:49 21 And then I also examined the role of price. So, was
03:38:54 22 there any evidence that the commercial success was importantly
03:38:57 23 being driven by the price of Vascepa.

03:38:59 24 And then finally looked at some of the marketing
03:39:03 25 documents and some analysis of physicians' perceptions of

03:39:07 1 Vascepa to see whether there was evidence that the patented
03:39:10 2 features were driving the awareness and the use of the
03:39:15 3 product.

03:39:16 4 MR. M. KENNEDY: Mr. Brooks, can we have
03:39:19 5 PDX 5-20.

03:39:19 6 BY MR. M. KENNEDY:

03:39:21 7 Q And, Dr. Nicholson, what does this slide show?

03:39:26 8 A So this shows for Lovaza at the top, and Vascepa at the
03:39:32 9 bottom, the marketing expenditures that were incurred for the
03:39:39 10 first six years of each of these drugs' life on the market.

03:39:43 11 So for Lovaza, that's 2005 to 2011. That's the
03:39:47 12 first six years when it was on the market, and Vascepa would
03:39:51 13 be 2013 through 2018.

03:39:53 14 So, that's what the numbers at the bottom refer to,
03:39:56 15 how many years since the drug launched.

03:39:59 16 Q Why did you choose that comparison?

03:40:01 17 A Well, Lovaza because it's -- it has a similar indication,
03:40:06 18 the same indication as Vascepa's initial indication.

03:40:10 19 But, I'm looking at the first six years because
03:40:15 20 marketing tends to be front-loaded. Pharmaceutical firms find
03:40:19 21 it most valuable to market their drug when it first launches
03:40:24 22 because information is more valuable at that point.

03:40:27 23 Some physicians aren't aware of the drug, or some
03:40:30 24 physicians might not be aware of how well the drug performed
03:40:33 25 in clinical trials. So, the marketing spending tends to be

03:40:37 1 higher early in a drug's lifecycle relative to later.

03:40:41 2 Q And where did you get the data to perform this
03:40:43 3 comparison?

03:40:44 4 A These data come from IQVIA.

03:40:46 5 Q And what kinds of marketing expenditures does IQVIA
03:40:52 6 collect for this type of comparison?

03:40:55 7 A IQVIA captures four different types of marketing
03:40:59 8 activities. So, money spent on the sales reps or the
03:41:03 9 detailing; the samples that are sometimes distributed to
03:41:08 10 physicians; advertisements in journals that physicians read;
03:41:12 11 and then finally, direct-to-consumer advertising.

03:41:16 12 Q And so the PX 642 and 647 are the data sources you used
03:41:23 13 for this slide?

03:41:24 14 A Yes, that's correct.

03:41:25 15 And if I could just speak to what the slide is
03:41:29 16 showing. What you can see is that the spending on Vascepa was
03:41:34 17 substantially lower in terms of marketing spending relative to
03:41:38 18 Lovaza at the same point in each of the two drugs' lifecycles.

03:41:42 19 So the spending on Vascepa's marketing ranged from
03:41:46 20 20 to 45 million per year. For Lovaza, it's more like 70 to
03:41:52 21 120 -- or 140 million.

03:41:54 22 Q So what significance do you ascribe to that disparity?

03:41:57 23 A Well, to me, this provides evidence that Amarin wasn't
03:42:03 24 marketing Vascepa more intensively than another similar
03:42:09 25 product, once you look at the same parts of their lifecycle.

03:42:13 1 MR. M. KENNEDY: Your Honor, we would like to
03:42:14 2 enter -- we'd move to enter PDX 5-20 as a summary exhibit
03:42:18 3 under FRE 1006.

03:42:21 4 MR. ROUNDS: No objection, Your Honor.

03:42:23 5 THE COURT: 5-20 is admitted.

03:42:26 6 MR. M. KENNEDY: And I'd also like to move
03:42:30 7 PX 642 and 647, to the extent they're not already admitted,
03:42:33 8 and Amarin would like a chance to review those for redactions
03:42:36 9 for publishing.

03:42:38 10 MR. ROUNDS: No objection.

03:42:39 11 THE COURT: All right. To the extent they
03:42:41 12 haven't been admitted, 642 and 647 are admitted.

03:42:41 13 (Plaintiffs' Exhibit 5-20, 647 and 642
03:42:41 received in evidence.)

03:42:50 14 MR. M. KENNEDY: Mr. Brooks, can we have 5-21,
03:42:53 15 please.

03:42:53 16 BY MR. M. KENNEDY:

03:42:56 17 Q And, Dr. Nicholson, what are you showing on this slide?

03:43:00 18 A So I'm showing another way to look at the marketing
03:43:03 19 intensity of Vascepa versus Lovaza. So the same six years
03:43:09 20 post-launch are being displayed on the horizontal axis. The
03:43:13 21 vertical axis is now the marketing to sales ratio. So, it's
03:43:17 22 the marketing spending in dollars, divided by the sales in
03:43:21 23 dollars.

03:43:23 24 And what you can see is those two lines, Vascepa and
03:43:26 25 Lovaza, are quite similar; or, in other words, when you take

03:43:29 1 an alternative way at measuring marketing, there's additional
03:43:33 2 evidence that Vascepa is not being marketed in an excessive
03:43:37 3 way relative to Lovaza.

03:43:39 4 Q And, again, you're relying on IQVIA data for these
03:43:47 5 comparisons?

03:43:48 6 A Yes.

03:43:49 7 MR. M. KENNEDY: Your Honor, we'd like to enter
03:43:50 8 PDX 5-21 as a summary exhibit under FRE 1006.

03:43:55 9 MR. ROUNDS: No objection, Your Honor.

03:43:56 10 THE COURT: 5-21 is admitted.

03:43:59 11 MR. M. KENNEDY: And I would also like to enter
03:44:01 12 PX 643 and PX 645. And again, we would ask for the
03:44:07 13 opportunity to review for redactions.

03:44:10 14 THE COURT: Any objection?

03:44:12 15 MR. ROUNDS: No objection, Your Honor.

03:44:12 16 THE COURT: All right. They're admitted.

03:44:12 17 (Plaintiffs' Exhibit 5-21, 643 and 645
03:44:12 received in evidence.)

03:44:12 18 BY MR. M. KENNEDY:

03:44:17 19 Q So, Dr. Nicholson, what is your overall conclusion as to
03:44:21 20 whether marketing expenditure is responsible for Vascepa's
03:44:21 21 commercial success?

03:44:23 22 A My conclusion is that it is not the driver of the
03:44:30 23 commercial success, that Amarin is not marketing Vascepa in a
03:44:33 24 more intensive way relative to the rest the industry, or
03:44:37 25 relative to a comparable product, Lovaza.

03:44:40 1 MR. M. KENNEDY: Mr. Brooks, can we have
03:44:43 2 DDX 8.18.

03:44:43 3 BY MR. M. KENNEDY:

03:44:45 4 Q And, Dr. Nicholson, do you remember this graph or pie
03:44:48 5 chart that Mr. Hofmann showed this morning?

03:44:51 6 A Yes.

03:44:52 7 Q Do you believe that this is an appropriate way to
03:44:55 8 evaluate promotional dollar spend from 2013 to 2017 for the
03:45:03 9 listed drugs?

03:45:04 10 A No, I don't believe so. This figure is collapsing five
03:45:08 11 years of data into a single figure.

03:45:11 12 And so I -- I mentioned it's important to look at
03:45:15 13 marketing spending according to where a drug is in its
03:45:20 14 lifecycle, because firms have strong incentives to market
03:45:24 15 early when there's relatively little known about the drug.

03:45:28 16 And here the other drugs all have -- so that's one
03:45:33 17 point, that rather than collapsing this into five years, the
03:45:36 18 appropriate thing would be to look year by year.

03:45:39 19 The other point is that all these other drugs,
03:45:41 20 except for Vascepa, had a generic version at some point in
03:45:45 21 this time period, and as was discussed this morning, generally
03:45:49 22 branded firms cease their marketing when they lose market
03:45:54 23 exclusivity, when a generic enters.

03:45:57 24 Q Now, you said -- do generic drugs and drugs that have
03:46:02 25 been in a given market longer tend to have comparative -- or a

competitive advantage of new entrants?

A In general, yes. All else equal, yes, because drugs that have been established in the market are well-known by prescribers and patients, and so they're able to establish a reputation and get some sort of a first mover advantage.

But also, once there are generics available, those products end up being much less expensive, and so they are well-known, established, and often much less expensive.

Q Now, a new drug like Vascepa coming into a market that, as we've seen, was largely genericized, how was it able to gain a foothold in that market?

A Well, in part, it needs to differentiate itself. It needs to provide information to health insurers, to patients, to physicians, what are the attributes of this drug, is this drug different from other drugs, and, if so, how is it different as a way of try to carve out a set of patients who are willing to take it.

Q And in terms of a differentiator, are you referring to clinical data?

A Certainly that would be an important differentiator, yes.

Q Have you reviewed how Amarin marketed its product to physicians?

A Yes, I have.

Q What was the message that we asked you to analyze for purposes of evaluating Amarin's marketing efforts?

03:47:35 1 A Well, I was asked to examine whether, and to what extent,
03:47:41 2 Amarin was featuring the patented features in its marketing;
03:47:46 3 specifically, the ability of Vascepa to reduce TG levels
03:47:52 4 without increasing LDL-C, and was that message resonating with
03:47:57 5 physicians, and was it important for their use of the product.

03:48:01 6 MR. M. KENNEDY: Mr. Brooks, can we have PX 580,
03:48:04 7 please.

03:48:04 8 BY MR. M. KENNEDY:

03:48:08 9 Q Dr. Nicholson, do you recognize this document?

03:48:11 10 A Yes. This is a study that a company called ZS Associates
03:48:16 11 produced for Amarin in August of 2014.

03:48:20 12 Q What is your understanding of the purpose of this report?

03:48:24 13 A My understanding is that Amarin was interested in
03:48:28 14 understanding are physicians aware of Vascepa, and, more
03:48:34 15 specifically, are they aware of specific attributes of
03:48:39 16 Vascepa, and does that attribute knowledge affect their use of
03:48:44 17 Vascepa.

03:48:45 18 Q Is this sort of the market research a typical thing that
03:48:48 19 pharmaceutical companies do to evaluate their marketing
03:48:52 20 messages?

03:48:53 21 A It is. Companies want to understand whether their
03:48:56 22 messages are resonating and whether decision-makers are
03:49:02 23 knowledgeable about the product.

03:49:03 24 Q Did you rely on PX 580 in forming your opinions in this
03:49:07 25 case?

03:49:07 1 A Yes.

03:49:09 2 MR. M. KENNEDY: Your Honor, we offer PX 580
03:49:12 3 into evidence.

03:49:13 4 MR. ROUNDS: No objection.

03:49:14 5 THE COURT: PX 580 is admitted.

03:49:14 6 (Plaintiffs' Exhibit 580 received in
03:49:14 evidence.)

03:49:18 7 MR. M. KENNEDY: Mr. Brooks, can we have page 6
03:49:20 8 of PX 580.

03:49:20 9 BY MR. M. KENNEDY:

03:49:23 10 Q And so, Dr. Nicholson, what were the take-away points
03:49:26 11 from this market survey in terms of Amarin's marketing?

03:49:31 12 A I'll focus on the bullet point about half-way in the
03:49:37 13 slide in the Marketing Effort section that says,

03:49:40 14 "A majority of the physicians (approximately
03:49:43 15 80 percent) recall Vascepa's LDL-C message."

03:49:47 16 That is, that it doesn't increase LDL-C bad
03:49:51 17 cholesterol.

03:49:52 18 And then below that, the physicians who are
03:49:54 19 prescribing Vascepa, who are using it, are more aware of that
03:50:00 20 attribute than physicians who are not currently prescribing
03:50:05 21 Vascepa.

03:50:05 22 So when a physician becomes aware of the ability
03:50:08 23 of Vascepa not to increase LDL-C, that increases their
03:50:11 24 probability of prescribing it.

03:50:14 25 MR. M. KENNEDY: Mr. Brooks, can we have

03:50:15 1 page 28, please.

03:50:15 2 BY MR. M. KENNEDY:

03:50:18 3 Q And there's a term on this page called "message recall."
03:50:22 4 What is message recall in this context?

03:50:25 5 A This is -- message recall is whether physicians were able
03:50:29 6 to identify a message that Amarin might be marketing to
03:50:37 7 physicians.

03:50:38 8 So Amarin's sales force might have talking points,
03:50:42 9 and the question is to what extent are physicians processing
03:50:47 10 that, understanding that.

03:50:48 11 Q And what did this data show in terms of what messages
03:50:53 12 physicians are recalling regarding Vascepa?

03:50:56 13 A Well, here, if I could focus on the first set of those
03:51:01 14 three bars towards the left.

03:51:03 15 MR. M. KENNEDY: Yeah. Mr. Brooks, if you could
03:51:06 16 blow those up a little bit.

03:51:11 17 THE WITNESS: In the messages section towards
03:51:14 18 the bottom, it says,

03:51:15 19 "Vascepa significantly reduced TG levels and
03:51:18 20 improved multiple lipid parameters without increasing
03:51:22 21 LDL-C."

03:51:23 22 So, those are two of the patented features.

03:51:26 23 And what the bars show you is -- the bar on the
03:51:29 24 left is that all of the physicians who are heavy users -- so
03:51:33 25 they're prescribing a relatively large number of Vascepa

03:51:37 1 prescriptions, all of those physicians were aware of those
03:51:40 2 attributes for Vascepa. Whereas the nonusers, that's the
03:51:46 3 73 percent, only 73 percent of the nonusers were aware of
03:51:49 4 that.

03:51:50 5 So in other words, the -- when physicians became
03:51:53 6 aware of those patented features, it increased the probability
03:51:57 7 that they were using Vascepa, or using it relatively heavily.

03:52:01 8 MR. M. KENNEDY: Mr. Brooks, can we have
03:52:08 9 page 57.

03:52:08 10 BY MR. M. KENNEDY:

03:52:09 11 Q And what did the survey conclude in terms of physicians'
03:52:13 12 intention to increase their Vascepa prescriptions?

03:52:17 13 A So the ZS analysis identified a group of physicians who
03:52:22 14 stated that they intend to increase their use of Vascepa.

03:52:25 15 And when asked why they intend to increase their use
03:52:29 16 of Vascepa, the two most common answers is, one, the attribute
03:52:36 17 that's in the dotted rectangle there.

03:52:38 18 The most common response was, you know, the
03:52:41 19 physician plans to increase the use because they understand
03:52:45 20 that Vascepa doesn't increase LDL-C.

03:52:48 21 The second most common is, you know, two down from
03:52:52 22 that, physicians highlighted that Vascepa is effective at
03:52:56 23 lowering TG levels, again, two of the patented features that
03:53:01 24 are involved in the lawsuit.

03:53:02 25 MR. M. KENNEDY: Mr. Brooks, can we have PX 581.

03:53:02 1 BY MR. M. KENNEDY:

03:53:09 2 Q Dr. Nicholson, do you recognize this document?

03:53:11 3 A Yes. This was a summary of a study that a company called
03:53:16 4 AplusA assembled and presented to Amarin in January of 2016.

03:53:23 5 Q Is this a survey similar to the one we just looked at,
03:53:26 6 just later in time?

03:53:28 7 A Yes, it is, in the sense of trying to understand are
03:53:32 8 physicians aware of Vascepa, and, more specifically, how
03:53:36 9 knowledgeable are they about the attributes.

03:53:39 10 Q Did they rely on PX 581 in forming your opinions in this
03:53:43 11 case?

03:53:44 12 A Yes.

03:53:45 13 MR. M. KENNEDY: Your Honor, we offer PX 581
03:53:48 14 into evidence.

03:53:49 15 MR. ROUNDS: No objection.

03:53:49 16 THE COURT: 581 is admitted.

03:53:49 17 (Plaintiffs' Exhibit 581 received in
03:53:49 18 evidence.)

03:53:53 18 MR. M. KENNEDY: Mr. Brooks, can we have page 8,
03:53:56 19 please.

03:53:56 20 BY MR. M. KENNEDY:

03:53:56 21 Q And I would like to focus, in particular, on the
03:53:59 22 left-hand side, the person lifting weights.

03:54:02 23 And with reference to that, Dr. Nicholson, what did
03:54:05 24 this survey find in terms of Vascepa's strengths in the
03:54:08 25 marketplace?

03:54:09 1 A So one conclusion is that, from the physician's
03:54:14 2 perspective, when studied, they indicate that some of the
03:54:17 3 strengths of Vascepa are that it's effective in lowering TG
03:54:22 4 levels and it doesn't increase LDL-C.

03:54:25 5 Q So similar to what we just looked at from 2014?

03:54:30 6 A Yes. Two of the patented features arising and resonated
03:54:37 7 with physicians.

03:54:38 8 MR. M. KENNEDY: Mr. Brooks, could we have
03:54:41 9 PX 577.

03:54:41 10 BY MR. M. KENNEDY:

03:54:45 11 Q And, Dr. Nicholson, do you recognize this document?

03:54:48 12 A Yes. This is a study conducted by the same company for
03:54:52 13 Amarin a little over a year after the one that we just looked
03:54:57 14 at.

03:54:57 15 Q Did you rely on PX 577 in forming your opinions in this
03:55:01 16 case?

03:55:01 17 A Yes.

03:55:03 18 MR. M. KENNEDY: Your Honor, Amarin offers
03:55:06 19 PX 577 into evidence.

03:55:07 20 MR. ROUNDS: No objection.

03:55:08 21 THE COURT: 577 is in admitted.

03:55:08 22 (Plaintiffs' Exhibit 577 received in
03:55:08 evidence.)

03:55:12 23 MR. M. KENNEDY: Mr. Brooks, can we have page 11
03:55:15 24 of this document.

03:55:15 25

03:55:15 1 BY MR. M. KENNEDY:

03:55:15 2 Q And, again, what did this survey find in terms of the key
03:55:20 3 strengths of the Vascepa brand as of 2017?

03:55:25 4 A So similar to the prior study, again, at the top, the key
03:55:29 5 strengths -- among the key strengths were efficacious in
03:55:33 6 lowering TG levels and does not increase LDL-C or bad
03:55:37 7 cholesterol.

03:55:38 8 MR. M. KENNEDY: Mr. Brooks, can we have PX 719.

03:55:38 9 BY MR. M. KENNEDY:

03:55:46 10 Q Dr. Nicholson, do you recognize PX 719?

03:55:50 11 A Yes. What this shows is if a patient or prospective
03:55:56 12 patient had gone to the Vascepa consumer part of the website
03:56:00 13 prior to the second indication, prior to December 2019, this
03:56:05 14 is what they would have seen.

03:56:07 15 And in the lower right, you can see that Amarin was
03:56:10 16 marketing the patented features; namely, Vascepa is proven to
03:56:15 17 lower very high TG levels in adults without raising bad
03:56:20 18 cholesterol.

03:56:21 19 Q Is PX 719 a document you relied on in forming your
03:56:25 20 opinions in this case?

03:56:26 21 A Yes.

03:56:27 22 MR. M. KENNEDY: Your Honor, Amarin seeks to
03:56:29 23 enter PX 719 into evidence.

03:56:33 24 MR. ROUNDS: No objection.

03:56:33 25

(Plaintiffs' Exhibit 719 received in evidence.)

BY MR. M. KENNEDY:

Q Now, what is your conclusion in how Amarin has promoted Vascepa to physicians?

A My conclusion is that from a quantity or an intensity perspective, they're marketing it with a similar intensity to the industry and to other products.

That they're featuring the messages that are at issue in the patent -- the patents that are issue in suit, and that those patented features are resonating with physicians, and physicians are often mentioning those as reasons for either using the product, or for planning to increase their use of the product.

So I don't find that the marketing is the driver of the commercial success.

MR. M. KENNEDY: Mr. Brooks, can we please have PDX 5-22.

BY MR. M. KENNEDY:

Q So, Dr. Nicholson, moving on to another topic, what does this slide show in terms of pricing for Vascepa versus Lovaza?

A So this shows between 2013 and 2018, what's the gross price per monthly prescription for Vascepa versus branded Lovaza versus generic Lovaza.

So the vertical axis is the price of a prescription, the gross price of a prescription, and what you can see, if

03:58:02 1 you focus on 2018, is that the gross price for a prescription
03:58:08 2 of Vascepa is about \$320, and that's substantially higher than
03:58:13 3 the gross price of generic Lovaza, which is about \$60.

03:58:19 4 Now, the reason I'm showing this is, in theory, you
03:58:23 5 know, another possible driver of commercial success would be
03:58:27 6 that Vascepa is offering its product -- or Amarin is offering
03:58:32 7 Vascepa at a very low price, and that's what's explaining the
03:58:35 8 numbers of prescriptions that are filled or the growth in
03:58:39 9 prescriptions. But, Vascepa's price is substantially higher
03:58:43 10 than generic Lovaza's price.

03:58:45 11 Q Now, where are you getting the data that appears in
03:58:49 12 PDX 5-22?

03:58:50 13 A These data come from IQVIA.

03:58:54 14 MR. M. KENNEDY: Your Honor, we would like to
03:58:55 15 admit PDX 5-22 as a summary exhibit under FRE 1006.

03:59:01 16 MR. ROUNDS: No objection, Your Honor.

03:59:02 17 THE COURT: 5-22 is admitted.

03:59:02 18 (Plaintiffs' Exhibit 5-22 received in
03:59:02 19 evidence.)

03:59:02 19 BY MR. M. KENNEDY:

03:59:07 20 Q Now, there was some discussion earlier about net sales --
03:59:10 21 or net price versus gross price, and net sales versus gross
03:59:14 22 sales. Does PDX 5-22 take into account rebates and discounts
03:59:19 23 and the like?

03:59:20 24 A No. This just takes into account what's called
03:59:25 25 "on-invoice adjustments," but it wouldn't capture rebates and

discounts.

If you take, say, the 53 percent rebate figure that Mr. Hofmann presented for 2018, and if one were to apply that to the Vascepa gross price, it would still be the case that Vascepa's priced two-and-a-half to three times higher than generic Lovaza. So that still wouldn't be a situation where people are filling Vascepa because it's a way for them to save money relative to generic Lovaza.

In other words, patients and insurers are paying a premium for the features of Vascepa relative to generic Lovaza.

MR. M. KENNEDY: And Your Honor, I would like to move admission of the underlying data for PDX 5-22, which is PX 644, PX 655, PX 659, and PX 660. And, again, we would like the opportunity to redact before they are published.

MR. ROUNDS: No objection, Your Honor.

THE COURT: All four exhibits are admitted.

(Plaintiffs' Exhibit 655 and 660 received in evidence.)

MR. M. KENNEDY: And, Mr. Brooks, if we go back to 5-15 very briefly.

BY MR. M. KENNEDY:

Q And this is your slide regarding cash flow?

A Yes.

Q What -- where do you get the data underlying PDX 5-15?

A These data came from a number of documents that are

04:00:59 1 enumerated at the bottom including financial statements
04:01:03 2 submitted to the SEC, and also the analyst reports, among
04:01:07 3 others.

04:01:08 4 MR. M. KENNEDY: Your Honor, I would like to
04:01:09 5 admit the ones that haven't been admitted yet from this slide,
04:01:12 6 and those are PX 628, 629, 630, 631, 633, 634, 635, 636, 645,
04:01:28 7 and 664.

04:01:32 8 MR. ROUNDS: No objection.

04:01:35 9 THE COURT: Those exhibits are admitted.

04:01:35 10 (Plaintiffs' Exhibit 628, 629, 230, 633,
04:01:35 11 634, 635, 636 and 645 received in
04:01:35 12 evidence.)

04:01:40 12 MR. M. KENNEDY: And, Your Honor, if we can go
04:01:42 13 to PDX 5-22 again.

04:01:46 14 And, I'm sorry, I'm told I misspoke. I meant to
04:01:50 15 move admission of PX 645, not 655.

04:01:57 16 THE COURT: I admitted 645.

04:02:01 17 MR. M. KENNEDY: Okay. Maybe I didn't misspeak.

04:02:03 18 THE COURT: Either that or it was admitted
04:02:04 19 earlier, I can't recall.

04:02:07 20 MR. M. KENNEDY: Sounds like I got the right
04:02:09 21 exhibit into evidence. Thank you.

04:02:12 22 Mr. Brooks, can we have exhibit PDX 5-23,
04:02:17 23 please.

04:02:17 24 BY MR. M. KENNEDY:

04:02:17 25 Q And, Dr. Nicholson, what does this slide show?

04:02:21 1 A This slide shows, for Lovaza, from 2008 to 2012, the
04:02:30 2 percentage of patients of different TG levels who were
04:02:34 3 receiving a prescription for Lovaza.

04:02:36 4 So, these data come from a dataset within IQVIA,
04:02:41 5 which is called NDTI, the National Disease and Therapeutic
04:02:46 6 Index.

04:02:47 7 Q And how, if at all, does this slide, PDX 5-23, support
04:02:52 8 your opinion?

04:02:53 9 A So when I showed earlier the net sales of Vascepa and the
04:02:59 10 trend in those sales, and when I used sales in the Net Present
04:03:04 11 Value analysis, I used all of the sales, the sales to patients
04:03:08 12 with very high TG levels, as well as the sales to patients
04:03:13 13 with high or normal and borderline high.

04:03:16 14 Q Well, why did you do that if the patents in this case are
04:03:19 15 limited to treating patients with very high triglycerides or
04:03:24 16 above 500 milligrams per deciliter?

04:03:27 17 A For several reasons. First, and, very importantly, for
04:03:31 18 purposes of commercial success and nonobviousness, it's
04:03:34 19 important to think about a situation where a company like
04:03:38 20 Amarin, in 2008, was considering developing a product like
04:03:44 21 Vascepa, and what would have been available to them is
04:03:47 22 information on the way in which Lovaza was being used at this
04:03:52 23 time in 2008.

04:03:53 24 And what you can see is in 2008 is a majority --
04:04:00 25 many of the prescriptions that were being filled by patients

1 for Lovaza were being filled by patients with high or normal
2 or borderline high.

3 So a company like Amarin considering developing a
4 drug like Vascepa, would have expected that if they could get
5 an indication for very high, it would give physicians an
6 opportunity to use their medical discretion to use Vascepa on
7 patients with high, normal, and borderline high.

8 Q Now, the sales that were enabled with the approval of the
9 MARINE indication, where did that money go? What did Amarin
10 do with that money?

11 A So that got, for the most part, invested in research and
12 development for the REDUCE-IT trial. So that's another
13 important reason for including all of the sales, not just the
14 sales of Vascepa to very high patients.

15 The indication that Amarin received in 2012, and the
16 launch of Vascepa in 2013, generated revenue or sales that
17 Amarin could use to finance the very expensive REDUCE-IT
18 trial.

19 Q And just to clean up a couple things, PDX 5-23, where did
20 you get the data that went into this slide?

21 A So these data come from IQVIA, but, more specifically,
22 the National Disease and Therapeutic Index dataset within
23 IQVIA.

24 MR. M. KENNEDY: Your Honor, we would like to
25 enter PDX 5-23 as a summary exhibit, and I would also like to

enter PX 641, with the reservation that we would like a chance to review for redactions.

MR. ROUNDS: No objection.

THE COURT: All right. That request is granted.

(Plaintiffs' Exhibit 5-23 and 641 received in evidence.)

MR. M. KENNEDY: And if we could briefly look at PDX 5-24.

BY MR. M. KENNEDY:

Q And then, Dr. Nicholson, what does this slide show?

A This is a similar slide. The setup is similar to the one that we just looked at, but now this is for Vascepa rather than Lovaza, and the years are different. It's the first six years that Vascepa was on the market.

The dark blue at the bottom is the percentage of patients whose TG levels are known that were taking Vascepa and had very high TG.

And you can see that it's -- that the dark blue here is substantially higher than the very high component of the Lovaza patient population.

But you can also see that a substantial percentage of the patients who are using Vascepa do have high and normal and borderline high, just as was the case with Lovaza.

Q Finally, were you in the courtroom this morning when Dr. Hof -- or Mr. Hofmann testified about his calculation of Vascepa net sales potentially covered by the asserted claims

04:07:00 1 of the patents-in-suit?

04:07:02 2 A Yes.

04:07:02 3 Q What's your understanding of how he made that
04:07:05 4 calculation?

04:07:08 5 A My understanding is he essentially took the percentages
04:07:12 6 of the dark blue segments here at the bottom and multiplied
04:07:18 7 that by the Vascepa sales for the corresponding years --

04:07:22 8 Q Uh --

04:07:23 9 A Sorry -- to get the estimated sales coming from the very
04:07:27 10 high patients.

04:07:28 11 Q And what's your understanding of what the Vascepa net
04:07:31 12 sales would look like if we just looked at those drug
04:07:34 13 appearances 500 and above?

04:07:38 14 A You would still see a substantial growth over time in the
04:07:43 15 sales, the estimated sales to the very high patients. I think
04:07:47 16 it's a six-fold increase over time in those sales.

04:07:50 17 Q How would that affect your conclusions concerning the
04:07:53 18 commercial success of Vascepa, if we just limited ourselves to
04:07:57 19 Mr. Hofmann's calculation concerning drug appearances above
04:08:01 20 500?

04:08:02 21 A It supports my conclusion that Vascepa is a commercial
04:08:07 22 success because it would show in a subset of patients that the
04:08:10 23 product is delivering value and that value is increasing over
04:08:15 24 time.

04:08:16 25 MR. M. KENNEDY: Thank you very much,

04:08:16 1 Dr. Nicholson. I have no further questions at this time.

04:08:19 2 THE COURT: Did you want to move to admit
04:08:22 3 Exhibit 5-24 as summary evidence?

04:08:25 4 MR. M. KENNEDY: Yes. Thank you, Your Honor. I
04:08:26 5 apologize. I would like to admit PDX 5-24, as well as the
04:08:31 6 underlying documents, PX 646 and 662, again, subject to the
04:08:36 7 opportunity to redact.

04:08:38 8 THE COURT: Any objection, Mr. Rounds?

04:08:40 9 MR. ROUNDS: No, Your Honor.

04:08:41 10 THE COURT: All right. That request is granted.

04:08:41 11 (Plaintiffs' Exhibit 5-24, 646 and 662
04:08:43 received in evidence.)

04:08:43 12 MR. M. KENNEDY: Thank you, Your Honor.

04:09:14 13 MR. ROUNDS: Dr. Nicholson, good afternoon.

04:09:16 14 THE WITNESS: Good afternoon.

04:09:26 15 MR. ROUNDS: My name is a Michael Rounds. I'll
04:09:27 16 be asking you questions on behalf of the defendants.

04:09:27 17 CROSS-EXAMINATION

04:09:27 18 BY MR. ROUNDS:

04:09:30 19 Q I would like to begin with, just briefly, discussing your
04:09:34 20 disclosures in your report.

04:09:36 21 Isn't it true that you have testified or provided
04:09:41 22 reports in approximately 23 cases in the last four years?

04:09:46 23 A I can't remember the precise number, but that sounds
04:09:50 24 about right.

04:09:51 25 Q Okay. And in a substantial portion of those cases, you

04:09:54 1 provided testimony on behalf of the branded pharmaceutical
04:09:57 2 companies; is that correct?

04:09:58 3 A A majority. Certainly, not all of them. I've had
04:10:05 4 generic clients.

04:10:06 5 Q Okay. So you understand that Amarin is asserting six
04:10:08 6 Orange Book listed patents against the defendants, correct?

04:10:12 7 A Yes, that's my understanding.

04:10:24 8 MR. ROUNDS: Okay. Can you pull up slide
04:10:28 9 PDX 5-3.

04:10:28 10 BY MR. ROUNDS:

04:10:34 11 Q Now, you were asked some questions by Mr. Kennedy about
04:10:37 12 this slide, do you recall that?

04:10:39 13 A Yes.

04:10:40 14 Q I just want to make sure that we're on the same page as
04:10:43 15 to what the claimed invention is in this case.

04:10:47 16 Everything you learned about what the claims covered
04:10:49 17 came from Amarin's counsel; is that right?

04:10:52 18 A Yes, that's correct.

04:10:54 19 Q Okay. And you understand from Amarin's counsel is that
04:10:58 20 the asserted patents are method of use patents; is that right?

04:11:03 21 A Yes.

04:11:03 22 Q Your understanding is that the patents do not cover the
04:11:08 23 EPA compound itself, is that correct?

04:11:11 24 A Yes, that's my understanding.

04:11:14 25 Q And your understanding is, is that in order to practice

1 the claims a patient has to have triglyceride levels of 500 or
2 more milligrams per deciliter, correct?

3 A I'm not a scientist. I don't understand that from a
4 scientific or legal perspective, but I do understand that the
5 patents refer to very high TG.

6 Q Okay. You understand that with respect to these patents
7 that a treated patient has to have triglyceride levels of 500
8 or more milligrams per deciliter, correct?

9 A My understanding is physicians have discretion to use
10 drugs in the way they think will benefit the patients.

11 Q Yeah, but I'm asking you with respect to the claims and
12 your understanding.

13 Is it your understanding that in order to practice
14 the claims, the patient has to have triglyceride levels of 500
15 or more milligrams per deciliter?

16 A I'm an economist. I didn't, as part of my assignment,
17 look at that question from a legal or scientific or medical
18 perspective.

19 MR. ROUNDS: If you can pull up deposition
20 transcript 52, lines 8 to 23, please.

21 BY MR. ROUNDS:

22 Q Do you see that?

23 A Yes.

24 Q So you were asked, beginning at line 8,

25 "I think we established earlier that you

1 hadn't reviewed the patents-in-suit, and thus you
2 hadn't reviewed the asserted claims of the
3 patents-in-suit, but if you could describe for me
4 your understanding of what is generally claimed in
5 the asserted claims of the patents-in-suit."

6 Do you see that?

7 A Yes.

04:13:02 8 Q And could you read your answer beginning at line 15.

04:13:05 9 A "My understanding is that the patents cover a
04:13:08 10 method of reducing triglyceride levels in patients
04:13:11 11 with severe hypertriglyceridemia without increasing
04:13:14 12 LDL-C."

04:13:15 13 Q Okay. And you understood and you understand that severe
04:13:19 14 hypertriglyceridemia is 500 milligrams or more of
04:13:26 15 triglycerides; is that fair?

04:13:28 16 A Yes.

04:13:29 17 Q Okay. So, back to my question.

04:13:38 18 You understand that the claimed invention includes
04:13:43 19 and requires a patient having triglyceride levels of 500 or
04:13:48 20 more milligrams per deciliter; is that fair?

04:13:54 21 A My understanding of the patents from counsel is that it's
04:13:56 22 a method of reducing TG levels, most patients with very high
04:14:02 23 TG, without increasing LDL-C.

04:14:04 24 Q Right.

04:14:05 25 A From a legal perspective, I don't know what constitutes

04:14:07 1 practicing or not practicing it.

04:14:09 2 Q Fair enough.

04:14:09 3 And with respect to the very high that you just
04:14:13 4 mentioned, that's 500 or more triglycerides per deciliter; is
04:14:16 5 that fair?

04:14:17 6 A Yes.

04:14:20 7 Q Next thing I want to cover with you is the patented
04:14:23 8 features. Do you see that?

04:14:25 9 A Yes.

04:14:29 10 Q Okay. And did you understand in performing your analysis
04:14:32 11 that the patented features included lowering triglycerides
04:14:36 12 amongst patients with very high triglyceride levels, without
04:14:40 13 increasing LDLs.

04:14:42 14 A Yes.

04:14:43 15 Q And, again, when you use the term "very high" there, you
04:14:47 16 mean 500 or more milligrams of triglycerides; is that fair?

04:14:53 17 A Yes.

04:15:04 18 Q Now, you reviewed and relied upon NDTI data in your
04:15:12 19 report; is that right?

04:15:12 20 A Yes.

04:15:13 21 Q And that stands for National Disease and Therapeutic
04:15:18 22 Index; is that correct?

04:15:19 23 A Yes, correct.

04:15:20 24 Q And that is sourced from IQVIA; is that right?

04:15:25 25 A Yes, IQVIA.

04:15:28 1 Q And you've relied upon that data in your report; is that
04:15:31 2 right?

04:15:31 3 A Yes, I have.

04:15:32 4 Q Okay. And the NDTI data showed you that approximately
04:15:42 5 one-third of the sales of Vascepa, from 2013 to 2018, related
04:15:47 6 to patients with severe hypertriglyceridemia; is that correct?

04:15:53 7 A Yes. That's approximately correct. Yes.

04:16:00 8 MR. ROUNDS: Can you pull up PDX 5-24.

04:16:00 9 BY MR. ROUNDS:

04:16:10 10 Q Do you recall being asked questions about PDX 5-24?

04:16:15 11 A Yes, I do.

04:16:16 12 Q Okay. So if we take a look at year 2018, for example,
04:16:24 13 approximately 25 percent of the sales relate to patients that
04:16:32 14 have triglyceride levels of 500 milligrams or more per
04:16:37 15 deciliter; is that fair?

04:16:38 16 A Yes. So, they have a diagnosis of having very high TG,
04:16:45 17 yes.

04:16:46 18 Q And I believe you testified at your deposition that you
04:16:52 19 understood that this data indicated that approximately
04:16:58 20 25 percent of the sales of Vascepa related to patients that
04:17:03 21 have TG levels of 500 or more; is that fair?

04:17:06 22 A Yeah. Or perhaps more correctly, they have a diagnosis
04:17:12 23 of a very high TG, yes.

04:17:15 24 Q And they were treated with Vascepa; is that right?

04:17:21 25 A Yes. That's what this figure shows, yes.

04:17:25 1 Q These are prescriptions that were provided for Vascepa
04:17:28 2 for this patient class; is that correct?

04:17:30 3 A By "patient class," you mean patients who have a
04:17:37 4 diagnosis of very high TG level?

04:17:40 5 Q That's correct.

04:17:41 6 A Yes.

04:17:42 7 Q So despite the fact that only approximately 33 percent of
04:17:50 8 the sales of Vascepa are covered by the claims, as you
04:17:53 9 understand them, you did not perform an NPV or other
04:17:58 10 profitability analysis related to this patient population; is
04:18:03 11 that right?

04:18:03 12 A I didn't because it wouldn't be appropriate.

04:18:05 13 Q Now, let's talk for a bit about profitability. You agree
04:18:29 14 that Amarin has not been profitable through at least 2018; is
04:18:34 15 that correct?

04:18:34 16 A As a company, yes, I would agree.

04:18:37 17 Q And the historical Amarin financial data you analyzed was
04:18:41 18 through 2018, correct?

04:18:42 19 A Yes. In some of the slides I'm looking at first quarter
04:18:50 20 of 2019, but in most of my analysis I'm using data through
04:18:57 21 2018.

04:18:57 22 Q And you relied on Amarin's SEC 10-K filings in your
04:19:02 23 opinions; is that correct?

04:19:04 24 A Those were some of my data sources, yes.

04:19:06 25 Q And in its SEC 10-K filings, Amarin states that Vascepa

04:19:13 1 may never be profitable; is that right?

04:19:16 2 A Amarin, like many publicly traded companies has what I
04:19:20 3 think is boilerplate language that just cautions investors
04:19:26 4 that there's uncertainties in their business model.

04:19:30 5 Q Do you think the SEC would consider that language to be
04:19:34 6 boilerplate?

04:19:35 7 A Probably not. But, that type of language appears in
04:19:38 8 almost every publicly traded company's SEC statements.

04:19:42 9 MR. ROUNDS: Could you pull up PX 655, page 3.

04:19:42 10 BY MR. ROUNDS:

04:19:53 11 Q I will represent to you that PX 655 is the 2018 10-K for
04:19:58 12 Amarin. If I could direct your attention to page 3, the third
04:20:05 13 paragraph.

04:20:08 14 A Okay.

04:20:12 15 MR. ROUNDS: And if you can highlight the last
04:20:14 16 two sentences for the record.

04:20:14 17 BY MR. ROUNDS:

04:20:26 18 Q Do you have that in front of you?

04:20:28 19 A Yes.

04:20:28 20 Q So it indicates,

04:20:29 21 "In addition, projections, assumptions, and
04:20:32 22 estimates of our future performance are necessarily
04:20:35 23 subject to a high degree of uncertainty and risk due
04:20:38 24 to a variety of factors, including those described in
04:20:42 25 risk factors in item 1A of part 1 of this annual

04:20:46 1 report on form 10-K."

04:20:48 2 Do you see that?

04:20:48 3 A Yes, I do.

04:20:49 4 Q So Amarin is representing to the public in its 10-K, that
04:20:55 5 its future projections are subject to a high degree of
04:20:58 6 uncertainty and risk; is that right?

04:21:00 7 A Yes. As I said, you know, companies as a common practice
04:21:06 8 do this, and I think they're just reminding investors that
04:21:10 9 prior performance is no guarantee of future performance.

04:21:13 10 Q But that's your experience with pharmaceutical companies
04:21:18 11 in general, isn't it, that they can be subject to a high
04:21:21 12 degree of risk?

04:21:23 13 A Yes, but it doesn't prevent them from very carefully
04:21:27 14 forecasting, to the best of their ability, the future
04:21:30 15 performance of their drug.

04:21:31 16 This is an industry that spends 50- to \$60 billion a
04:21:36 17 year, and you don't spend that amount of money without doing
04:21:39 18 the best you can at forecasting.

04:21:41 19 Q So Amarin's 10-K filings are signed by its officers; is
04:21:45 20 that right?

04:21:45 21 A I believe so, yes.

04:21:47 22 Q Including the president, Mr. Thero, whom you spoke with
04:21:51 23 about your opinions in this case; is that right?

04:21:53 24 A Yes.

04:21:54 25 Q You never spoke with anybody else from Amarin, did you,

04:21:58 1 other than Mr. Thero?

04:22:00 2 A Correct, not prior to submitting the reports, yes.

04:22:03 3 Q So you never spoke to Mr. Berg prior to submitting your
04:22:08 4 reports?

04:22:08 5 A I don't believe so, no.

04:22:10 6 Q Okay. Do you think his input on how Vascepa was being
04:22:13 7 marketed and sold would be important to your opinions in this
04:22:15 8 case?

04:22:16 9 A I didn't. No, I didn't think it would be germane. I
04:22:21 10 wanted to look at the actual documents.

04:22:23 11 Q Okay. In any event, you agree with Amarin's officers,
04:22:26 12 don't you, that future projections for Vascepa are subject to
04:22:30 13 a high degree of uncertainty and risk?

04:22:33 14 A I mean, personally, I'm not sure I would use the "high
04:22:36 15 degree" adjective.

04:22:38 16 I think, you know, I don't know that they're subject
04:22:41 17 to any more uncertainty than other companies in this space,
04:22:45 18 but I do agree that there is uncertainty when you're
04:22:49 19 forecasting.

04:22:52 20 MR. ROUNDS: So can you pull up PDX 5-16.

04:22:52 21 BY MR. ROUNDS:

04:23:06 22 Q Do you have 5-16 in front of you?

04:23:08 23 A Yes, I'm sorry.

04:23:11 24 Q So the information on the left-hand side of this, as I
04:23:15 25 understand it, is based upon Amarin's historical financial

04:23:22 1 data; is that right?

04:23:23 2 A Yes, through the 2018 part of that line.

04:23:28 3 Q Okay. And those numbers are reflected in 2019 dollars;
04:23:32 4 is that right?

04:23:33 5 A Yes. From a discounting perspective, yes.

04:23:36 6 Q So through 2018, under your calculations Amarin shows a
04:23:41 7 net income loss of approximately 1.2 billion; is that right?

04:23:45 8 A Yes, I think that's the cumulative figure. Yes.

04:23:48 9 Q Okay. So let's switch gears here for a second.

04:23:51 10 You agree that the markets for pharmaceutical
04:23:53 11 products can change over time; is that correct?

04:23:56 12 A Yes, they can become more favorable or less favorable.

04:24:01 13 Q Is it fair to say that the uncertainty associated with a
04:24:05 14 forecast is significantly more than the uncertainty associated
04:24:09 15 with the actual historical results of a pharmaceutical
04:24:12 16 product?

04:24:13 17 A I think that's true in any industry, that the future
04:24:16 18 forecasts are always less certain than the past reality.

04:24:20 19 Q You also agree that future projections or forecasts for
04:24:26 20 pharmaceutical companies can be lower than expected; is that
04:24:29 21 right?

04:24:29 22 A They can be lower, and, as I showed, they can be higher.

04:24:32 23 Q And that the longer period -- strike that.

04:24:35 24 And that the longer the period of the forecast, the
04:24:38 25 less reliable it is; is that fair?

04:24:41 1 A That's generally what economists believe, that it's
04:24:44 2 easier to forecast closer in the horizon than further out.

04:24:49 3 Q Okay. You would agree that generally speaking all
04:24:51 4 companies hope that the products they develop and launch are
04:24:54 5 going to be economically successful, correct?

04:24:57 6 A Well, I certainly believe that there's a chief financial
04:25:03 7 officer whose job is to carefully shepherd the company's
04:25:08 8 money.

04:25:09 9 And so if, for example, a scientist has some
04:25:11 10 aspiration, it's not the case in my experience that the CFO
04:25:16 11 will say, you know, here's a blank check.

04:25:20 12 Q I guess the point is, is that everybody has hopes and
04:25:25 13 wishes when they're forecasting and trying to get a company
04:25:28 14 going; is that right?

04:25:29 15 A Yes, but we're talking about real money. When investors
04:25:33 16 give a company real money, they expect a return. And there
04:25:36 17 are consequences if they don't get a return.

04:25:38 18 Q We'll talk about the real money in a minute. Okay?

04:25:41 19 Also, generally speaking, you would agree that
04:25:45 20 companies will often produce forecasts of expected sales that
04:25:49 21 may or may not ever occur, right?

04:25:51 22 A Yeah. You know, I think I believe, like most economists,
04:25:57 23 that forecasts can some -- they're as accurate as people can
04:25:59 24 make them with the available information. Sometimes they're
04:26:02 25 high, sometimes they're low, sometimes they're spot on.

04:26:05 1 Q So let's go to your NPV calculations in this matter.

04:26:12 2 You did two different models, right, one with the
04:26:16 3 H.C. WainWright forecast and one without?

04:26:19 4 A No, I have one model, the model with the \$1.9 billion Net
04:26:23 5 Present Value.

04:26:23 6 Q But you did an alternative one that excluded the H.C.
04:26:27 7 WainWright; is that right?

04:26:28 8 A I wouldn't call -- that's not a revised model. I was
04:26:32 9 making the point that all five analysts' reports should be
04:26:37 10 included to maximize the accuracy of the forecast.

04:26:41 11 If one mistakenly omitted one of them -- which I
04:26:47 12 don't adhere to -- it would still be a positive Net Present
04:26:51 13 Value conclusion.

04:26:51 14 So, I wasn't revising my model, I was just
04:26:56 15 highlighting that it would still be a positive Net Present
04:26:58 16 Value.

04:26:59 17 Q Okay. Well, we'll get back to that.

04:27:00 18 In each of your NPV calculations you assumed that
04:27:09 19 Vascepa had market exclusivity until 2029 when Teva could
04:27:15 20 enter the market with a generic version of Vascepa, correct?

04:27:19 21 A Yes.

04:27:19 22 Q But if a generic were to enter the market three to
04:27:23 23 five months from now, you would agree that Vascepa is not
04:27:25 24 commercially successful through today's date; is that right?

04:27:29 25 A Yeah. In that hypothetical -- which I didn't consider --

04:27:32 1 yes. The prior losses would still prevail -- would prevail.

04:27:38 2 Q Yeah. In fact, under your NPV calculation, the company
04:27:43 3 would be in the hole about \$1.2 billion, right?

04:27:47 4 A I think that that's why we're here in this court, but I'm
04:27:52 5 modeling this with the information of there's a public
04:27:56 6 announcement about when Teva is able to enter, and that's the
04:28:01 7 period that's defining the end of the lifecycle in my model.

04:28:05 8 Q Now, I think, as you've testified, your Net Present Value
04:28:11 9 model is based on the financial forecasts of, I think, five
04:28:14 10 industry analysts; is that right?

04:28:16 11 A Yes.

04:28:17 12 Q And you did not check the credentials of any of the
04:28:21 13 specific industry analysts who wrote the reports; is that
04:28:25 14 right?

04:28:25 15 A I'm familiar with the company names. I'm familiar with
04:28:29 16 them, and I believe they are reputable. And in my reply
04:28:32 17 report, in responding to Mr. Hofmann, I did show that the
04:28:37 18 forecast errors can go both ways.

04:28:40 19 Q Back to my question. You didn't check the credentials of
04:28:47 20 any of the industry analysts who actually wrote these reports;
04:28:50 21 is that right?

04:28:52 22 A Well, I -- I think highly of the firms, and I know that
04:28:56 23 this is a profession that's regulated. One can become a
04:29:01 24 Certified Financial Analyst, and there are organizations that
04:29:05 25 try to uphold the standards of that profession.

04:29:08 1 Q So, Dr. Nicholson, please focus on my question.

04:29:11 2 Did you contact any of these analysts to discuss
04:29:14 3 these projections with them?

04:29:16 4 A No, I didn't reach out or didn't do any independent
04:29:20 5 evaluation of their credentials.

04:29:22 6 Q Okay. Fair enough.

04:29:23 7 You just took their word for what they were
04:29:28 8 projecting; is that right?

04:29:30 9 A Well, I've studied this industry for a while. I know
04:29:35 10 that these analysts are trying very hard to be accurate
04:29:38 11 because that's what makes -- gives the firm a reputation and
04:29:46 12 gives investors a reason to listen to what they're saying.

04:29:50 13 So if they do a poor job, they will pay consequences
04:29:54 14 in terms of their revenue. So this is something that they
04:29:57 15 take, in my experience, very seriously.

04:30:00 16 Q At least one of the analysts, Citi Research, said that
04:30:04 17 Amarin was a high risk stock; is that right?

04:30:07 18 A I can't -- I can't recall that now.

04:30:10 19 MR. ROUNDS: Can you pull up PX 657, and go to
04:30:18 20 page 7711.

04:30:18 21 BY MR. ROUNDS:

04:30:35 22 Q Do you have that exhibit in front of you?

04:30:37 23 A Yes, I do.

04:30:38 24 Q And do you see that under Risks, it indicates,

04:30:41 25 "We rate Amarin high risk, given the

04:30:43 1 historical and anticipated volatility in stock price
04:30:48 2 that is common for biotech stocks"?

04:30:50 3 A Yes.

04:30:51 4 Q And you would agree with that, right?

04:30:53 5 A I would agree that pharmaceutical and biotech companies
04:31:00 6 that have a relatively small number of drugs either in
04:31:02 7 development or in the market will be more volatile than
04:31:07 8 pharmaceutical firms that have a very large portfolio of
04:31:11 9 drugs. So, yes, I would agree with that.

04:31:12 10 Q Okay. My question is a little more specific.

04:31:15 11 Would you agree with Citi, who you're relying upon
04:31:18 12 in your report, that the Amarin stock is a high risk stock?

04:31:23 13 A I'm not disagreeing. There's a difference between the
04:31:28 14 volatility of the stock price and sales forecast. I mean,
04:31:31 15 they're somewhat related, but one is looking at the company's
04:31:35 16 value, and one is looking at the future performance of a
04:31:39 17 product.

04:31:39 18 Q Well, stock price is typically driven by sales and sales
04:31:44 19 forecasts; is that right?

04:31:45 20 A As a general matter, changes in stock price are driven
04:31:50 21 by -- well, stock price is based on expectations. Changes is
04:31:55 22 based on what actually occurs relative to those expectations.

04:32:02 23 Q In any event, did you work into your analysis that Citi
04:32:09 24 had indicated that Amarin was a high risk stock?

04:32:15 25 A Well, I did in the sense of trying to seek out as many

04:32:23 1 analysts' reports as I could that were forecasting sales and
04:32:27 2 operating margin of Vascepa in order to try to get a -- as
04:32:30 3 accurate as possible, and as, you know, stable rather than
04:32:33 4 volatile as possible forecast.

04:32:36 5 Q Let me direct your attention, if I could, to DDX 8.9.

04:32:48 6 I believe that we had discussed this earlier. This
04:32:52 7 was a slide that had been created by Mr. Hofmann. Do you
04:32:56 8 recall that?

04:32:56 9 A Yes.

04:32:57 10 Q And you can see that with respect to net revenue, that
04:33:03 11 the variance that it projected, had been projected by
04:33:08 12 Wainwright for 2018, was about 156 million; is that right?

04:33:12 13 A Yes, for 2018, yes.

04:33:14 14 Q And I believe you testified in your direct testimony that
04:33:19 15 sometimes these analysts can be a little high and a little
04:33:23 16 low; is that right?

04:33:24 17 A Yes.

04:33:24 18 Q Okay. So would you call a \$156 million variance a little
04:33:33 19 low?

04:33:35 20 A Well, it's -- I mean, it's a percentage. It's a pretty
04:33:39 21 big number. So I think, yes, there's uncertainty.

04:33:42 22 I think each of these five analysts is using all the
04:33:46 23 available information to try to do as well as they can.

04:33:49 24 I did show that sometimes the variance is positive
04:33:54 25 in the sense that this analyst is, in a couple of cases,

04:34:00 1 underestimating rather than overestimating.

04:34:02 2 But, no, I would characterize that as a fairly large
04:34:05 3 percentage difference.

04:34:06 4 Q Okay. They weren't just a little wrong, isn't that
04:34:12 5 right?

04:34:14 6 A Well, it's hard to define a little and a lot. I don't
04:34:18 7 know what the -- I didn't look at a benchmark to see what the
04:34:22 8 common variance is.

04:34:23 9 Q Well, you would agree that a \$156 million swing for a
04:34:28 10 company the size of Amarin is not a small number; is that
04:34:32 11 fair?

04:34:33 12 A It's possible. But I think, you know, there's two
04:34:37 13 benefits of using a large, in a sense of a five-analyst sample
04:34:41 14 as opposed to, say, one or two.

04:34:42 15 Q That's not the question, sir. Let's just focus on what
04:34:46 16 we're focused on right here.

04:34:48 17 Is a variance of \$157 million for a company the size
04:34:52 18 of Amarin a big number? It is, isn't it?

04:34:57 19 A Well, you know, I think the market cap of Amarin now is
04:35:01 20 in the billions. So, in that sense, you know, it's not large
04:35:04 21 when you think about a \$7 billion market cap.

04:35:08 22 But, again, my -- my sense is the Wainwright analyst
04:35:12 23 was doing as well as possible.

04:35:14 24 The variance of the forecast is going to go down
04:35:17 25 when I'm using more than just one analyst report. That's

04:35:21 1 another of the benefits of using many. You get a more precise
04:35:25 2 mean estimate and a smaller variance.

04:35:27 3 Q Okay. The market cap of billions that you're referring
04:35:31 4 to is a result of the recent change of the indication on the
04:35:35 5 label as a result of the REDUCE-IT study; is that right?

04:35:39 6 A I didn't do an analysis to decompose that market cap.

04:35:44 7 Q Okay. But as of the time that you did your report, the
04:35:49 8 \$156 million swing that we're looking at in DDX 8.9 was a big
04:35:55 9 number as it compared to the size of the company in its sales,
04:35:59 10 right?

04:35:59 11 A It may or may not have been. You know, keep in mind that
04:36:03 12 I'm not using -- you know, I wasn't using the WainWright
04:36:07 13 forecast for 2018. For 2018, I'm using the actual sales.

04:36:12 14 So, you know, this, this variance doesn't enter into
04:36:17 15 my NPV model. I'm using the 228.4 that was actually received.
04:36:24 16 So, my NPV model is not skewed by this variance.

04:36:28 17 Q Right. But you understand our point, right, that the
04:36:31 18 credibility of WainWright with respect to these particular
04:36:34 19 projections is not real good given this big swing. You get
04:36:40 20 that, right?

04:36:40 21 A No. I mean, I think I showed -- you know, what's built
04:36:43 22 into my NPV are a couple of periods when WainWright was overly
04:36:48 23 pessimistic, and also, for that matter, I'll concede that
04:36:51 24 WainWright was pretty darn close on some of those operating
04:36:56 25 margins. They were within a million dollars.

04:36:58 1 Q Let me ask you this question. Why didn't you do your own
04:37:02 2 NPV analysis instead of relying upon what you consider to be
04:37:06 3 experts that are doing projections in the industry?

04:37:10 4 A It is my NPV analysis. I'm using as inputs some
04:37:14 5 information from analysts.

04:37:15 6 I think if I were up here and I did my NPV analysis
04:37:20 7 and I just wrote down what I thought the sales would be, I
04:37:23 8 could imagine that someone would say, well, you know, you've
04:37:26 9 been hired by Amarin, you'll just put any sort of sales down.

04:37:30 10 Here I'm looking at people's whose livelihood, whose
04:37:35 11 profession depends on their accuracy. To me, that's a more
04:37:38 12 objective approach. I'm incorporating it into my model.

04:37:40 13 But I'm using things that were created in the course
04:37:43 14 of business for people who have incentive to be as accurate as
04:37:47 15 possible.

04:37:48 16 Q Yeah, but the point is that you're relying upon these
04:37:50 17 industry analysts that you believe are experts instead of
04:37:55 18 doing your own analysis to determine what you think the
04:37:58 19 projections might be until 2029; isn't that true?

04:38:04 20 A I identified a set of analysts that I believe are
04:38:08 21 reputable. I understand that, you know, they have rewards for
04:38:14 22 being as accurate as possible. I think if they just wrote
04:38:17 23 down a number, they wouldn't last very long in the profession.

04:38:21 24 Q Well, let's take a look, just quickly, back at DDX 8.9.

04:38:27 25 Do you see the second graph in which there's a

04:38:33 1 representation that WainWright was wrong as well with respect
04:38:36 2 to operating income?

04:38:40 3 A Yes, I see that.

04:38:42 4 Q Okay. And the variances there were 237 million, 192
04:38:47 5 million, and 185 million; is that right?

04:38:49 6 A Yes. For the three separate times when those forecasts
04:38:54 7 were made, yes.

04:38:55 8 Q Right. So we can agree, can't we, that those aren't
04:38:58 9 little differences, right?

04:39:00 10 A Well, again, I'm using the actual figure for 2018 in my
04:39:05 11 NPV. Again, I showed an instance where WainWright almost got
04:39:11 12 spot-on the operating income. It was still a little bit too
04:39:15 13 pessimistic.

04:39:16 14 And, you know, the two instances where they were
04:39:19 15 overly pessimistic, those are built into my NPV. So, those
04:39:24 16 would be pulling the numbers down.

04:39:26 17 Q But you used the actual as opposed to the forecast
04:39:29 18 because that's the better way to do it, right?

04:39:32 19 A Well, when one has actual data, it clearly is the
04:39:37 20 appropriate -- in most cases, the appropriate thing to use.

04:39:40 21 But I absolutely believe you need to analyze a drug
04:39:44 22 through its entire lifecycle. So just ceasing the analysis at
04:39:50 23 2018 is absolutely not appropriate given the way that this
04:39:53 24 industry works.

04:40:06 25 MR. ROUNDS: Can you pull up DX 1684, and go

04:40:10 1 to -- well, just pull that up initially.

04:40:12 2 I'm going to show you what's been marked as
04:40:19 3 DX 1684 which is your reply expert report?

04:40:22 4 A Yes.

04:40:23 5 Q Do you see that?

04:40:24 6 A Yes.

04:40:34 7 MR. ROUNDS: And can you go to page 56. Can you
04:40:41 8 pull that up?

04:40:41 9 BY MR. ROUNDS:

04:40:43 10 Q I believe that you were shown this previously by your
04:40:46 11 counsel?

04:40:47 12 A I think it came up in Mr. Hofmann's testimony.

04:40:51 13 Q Okay. You don't think you saw this today during your
04:40:55 14 testimony?

04:40:57 15 A Not this -- I don't remember seeing this specific --

04:41:00 16 Q Okay. Fair enough.

04:41:01 17 A Yes. This is in my report. I'm not disowning it.

04:41:04 18 Q That's okay. I thought this had been shown to you
04:41:06 19 previously. If I'm mistaken, that's on me.

04:41:08 20 So let's take a look at the Net Present Value by
04:41:12 21 analyst, 2008 to 2029. It's Exhibit 2 to your reply report.

04:41:18 22 Do you see that?

04:41:19 23 A Yes.

04:41:19 24 Q And in this forecast, if you will, Wainwright was looking
04:41:32 25 at about \$7.9 billion for a Net Present Value; is that

04:41:39 1 correct?

04:41:39 2 A Yes. Or, if I were to just use the WainWright data in my
04:41:45 3 model, that would be the Net Present Value. Yes.

04:41:50 4 Q Right. And Jefferies was about 600 million in the
04:41:53 5 negative; is that right?

04:41:54 6 A Yes. Again, using their forecasts, just their forecasts
04:42:01 7 in the model, that's what would be the associated NPV.

04:42:04 8 Q So why didn't the difference of \$7.3 billion between
04:42:09 9 these two analysts, give you any concern with respect to your
04:42:13 10 projections in this case?

04:42:15 11 A Now, some of it is due to my conservative decisions. I
04:42:21 12 mean, by taking the operating margin and assuming that it's
04:42:24 13 going to be constant beyond the analyst forecast window, I
04:42:30 14 mean, that's one explanation for why you get some of this
04:42:33 15 variance. So some of this is from my being conservative.

04:42:37 16 The median NPV is positive. That's another way to
04:42:41 17 address variation and variance. And, importantly, the mean,
04:42:45 18 which is what I use in my model, is positive across these.

04:42:49 19 Q Back to my question.

04:42:51 20 You weren't concerned at all, looking at a
04:42:56 21 \$7.2 billion difference, between WainWright and Jefferies,
04:43:01 22 that there could be some problems with your projections in
04:43:04 23 this case?

04:43:06 24 A No. I'm using reputable reports that are providing
04:43:12 25 important information to investors for them to invest millions

04:43:17 1 or billions of dollars, I'm doing it in an objective way, and,
04:43:22 2 I'm using all five to improve the accuracy, acknowledging that
04:43:25 3 there are going to be instances where analysts will be too
04:43:29 4 high and too low, and that's the point of averaging.

04:43:33 5 Q Right. But the truth is you don't really know what the
04:43:35 6 deal is going to be in 2029, right?

04:43:39 7 A I believe I've constructed a valid and accurate model
04:43:46 8 that's consistent with the way this industry analyzes the
04:43:50 9 lifecycle profits of a drug.

04:43:54 10 THE COURT: Mr. Rounds, I don't know if you've
04:43:57 11 identified the exhibit for -- where this document comes from.

04:44:02 12 MR. ROUNDS: Yeah, it's his reply report, Your
04:44:04 13 Honor.

04:44:04 14 THE COURT: Was it -- has it been marked as an
04:44:05 15 exhibit?

04:44:06 16 THE CLERK: 1684, Your Honor.

04:44:07 17 THE COURT: 1684?

04:44:09 18 THE CLERK: Yes.

04:44:10 19 THE COURT: Thank you.

04:44:12 20 MR. M. KENNEDY: We object to entering his
04:44:14 21 expert report as an exhibit, if that's --

04:44:16 22 THE COURT: I'm not, I just wanted to reference
04:44:18 23 it for identification. Thank you.

04:44:23 24 MR. ROUNDS: Well, Your Honor, if this has not
04:44:25 25 been entered into evidence, I would like to enter Exhibit 2 of

04:44:29 1 his reply report.

04:44:30 2 THE COURT: Any objection to just admitting
04:44:33 3 Exhibit 2?

04:44:34 4 MR. M. KENNEDY: No objection, Your Honor.

04:44:35 5 THE COURT: All right. So --

04:44:47 6 THE CLERK: The last marked exhibit is 2299.
04:44:51 7 Shall we mark it 2300?

04:44:58 8 THE COURT: You think we should mark it as 2300?

04:45:01 9 All right. We'll mark this -- so I know that
04:45:04 10 Exhibit 2 comes from an exhibit that's marked at 1684. What
04:45:10 11 I'll do is I will have a copy of Exhibit 2 separately admitted
04:45:15 12 as Exhibit 2300.

04:45:22 13 Any objection to that approach?

04:45:24 14 MR. M. KENNEDY: No objection, Your Honor.

04:45:26 15 MR. ROUNDS: No, Your Honor.

04:45:27 16 MR. SIPES: Your Honor, I believe if it would
04:45:28 17 help the Court, we could submit, you know, an excerpt exhibit
04:45:31 18 that would then have a separate number to it that would be
04:45:34 19 just the Exhibit 2. You know, the number may be A or
04:45:37 20 something, so there's no confusion, if that would be best
04:45:41 21 thing.

04:45:41 22 THE COURT: Well, sometimes what I do is I mark
04:45:45 23 and admit the exhibit as part of a document as -- for example,
04:45:50 24 this one would be -- one option is 1684-1.

04:45:54 25 MR. SIPES: That's fine. That sounds perfect,

04:45:57 1 Your Honor.

04:45:57 2 THE COURT: That may be easier.

04:45:59 3 So, I'll admit Exhibit 2 as 1684-1 -- or did we
04:46:07 4 do that dash A? Have I started that process yet?

04:46:16 5 (Discussion held off the record.)

04:46:16 6 THE COURT: All right. This will be 1685-A, as
04:46:27 7 in apple.

04:46:27 8 (Defendants' Exhibit 1685-A received in
04:46:27 evidence.)

04:46:34 9 THE COURT: All right. Sorry, Mr. Rounds, you
04:46:35 10 may resume.

04:46:37 11 MR. ROUNDS: Thank you, Your Honor.

04:46:37 12 BY MR. ROUNDS:

04:46:39 13 Q Now, not all of the analysts that you relied upon
04:46:42 14 projected potential future revenues for the ten-year period
04:46:46 15 out to 2029; is that right?

04:46:48 16 A Yes, that's correct.

04:46:49 17 Q Okay. In fact, two of the five analysts provided
04:46:52 18 projections from only 2019 to 2020; is that right?

04:46:57 19 A Yes. I believe that's correct, yes.

04:47:02 20 Q Okay. And that was Citi and Jefferies; is that correct?

04:47:04 21 A You know, I can't remember which ones they were.

04:47:08 22 Q So, in any event, with respect to these two analysts, you
04:47:15 23 did your own calculations of their projections from 2021
04:47:21 24 through 2029; is that right?

04:47:23 25 A Yeah. I extended, or extrapolated, in what I believed to

04:47:29 1 be a conservative fashion to create consistency across the
04:47:34 2 five.

04:47:35 3 MR. ROUNDS: Could you pull up PX 657.

04:47:35 4 BY MR. ROUNDS:

04:47:43 5 Q Do you recognize PX 657 as the Citi analyst's report that
04:47:51 6 you relied upon?

04:47:53 7 A Yes.

04:47:58 8 MR. ROUNDS: Can you go to page 2.

04:47:58 9 BY MR. ROUNDS:

04:48:04 10 Q And do you see at the very top there's a projected sales
04:48:09 11 revenue of approximately 542 million for 2020?

04:48:18 12 A Yes.

04:48:19 13 Q In your extrapolation of Citi's forecast, you assumed
04:48:25 14 Vascepa sales of approximately \$2 billion in 2028; is that
04:48:30 15 correct?

04:48:30 16 A I can't remember the -- you mean for this analyst? Are
04:48:38 17 you saying for this analyst --

04:48:38 18 Q Yes.

04:48:40 19 A -- or the average across the five? I can't remember what
04:48:42 20 it is precisely.

04:48:44 21 Q Does that sound right to you?

04:48:46 22 A You know, I don't know that that's wrong. I just can't
04:48:51 23 remember the figure for 2028.

04:48:53 24 Q Okay. You would agree, wouldn't you, that 20 billion is
04:48:57 25 roughly 3.7 times greater than Citi's actual forecast of 541

04:49:04 1 million for 2020?

04:49:05 2 A I think you said 20 billion. Do you mean 2.8 billion
04:49:10 3 or --

04:49:10 4 Q Let me ask it again.

04:49:13 5 Assume, if you will, that your projection says that
04:49:17 6 through 2028 Citi forecasts Vascepa sales of approximately 2
04:49:24 7 billion. That appears in your report. I'm making that
04:49:27 8 representation to you.

04:49:29 9 You would agree that 2 billion is roughly at least
04:49:34 10 3.7 times greater than the forecast Citi did of 541 million in
04:49:40 11 2020; is that right?

04:49:41 12 A Yeah. So what I did is I took the change between 350.5,
04:49:50 13 the forecast for 2019, and the forecast for 2020, so that's --
04:49:55 14 you know, let's just call it 190 million, and then assumed
04:49:59 15 that the sales forecast would increase by that 190 million
04:50:03 16 thereafter, which is associated with a declining growth rate
04:50:07 17 when measured as a percentage because the base is getting
04:50:10 18 bigger, that's the conservative nature of it.

04:50:13 19 But, yes, if you run that out, 190 million a year
04:50:17 20 for eight years, it becomes something that I'll accept your
04:50:23 21 characterization as 2 billion.

04:50:25 22 Q But you have no idea as you sit here whether the analysts
04:50:30 23 would agree with you in terms of the way you've run their
04:50:33 24 numbers from 2020 and equated them with your final result in
04:50:38 25 2028, isn't that true?

04:50:41 1 A That's right. I've used as inputs the analysts' data as
04:50:46 2 it was constructed, and I've made decisions that I believe
04:50:50 3 produce a model that's accurate and consistent and represents
04:50:55 4 how companies value drugs and how they evaluate commercial
04:51:02 5 success.

04:51:03 6 Q So just so we all understand here, after you applied the
04:51:13 7 discount rate, you essentially averaged the five forecasts of
04:51:18 8 projected income for the years 2019 to 2029 as part of your
04:51:22 9 NPV calculation; is that fair?

04:51:25 10 A Yes. I'm averaging the profits, the cash flows, and then
04:51:30 11 applying the discount rate, yes.

04:51:32 12 Q So you did no analysis on your own to determine which of
04:51:38 13 these analysts you deemed to be the most accurate with respect
04:51:43 14 to their projections; is that fair?

04:51:45 15 A Correct. I treated each of them equally in the sense of
04:51:49 16 I'm using a straight average across the five. I'm not
04:51:53 17 applying a weight, which would be different than 20 percent
04:52:02 18 for each.

04:52:07 19 MR. ROUNDS: Can you pull up 1684 again, his
04:52:12 20 reply report, and go to page 55.

04:52:12 21 BY MR. ROUNDS:

04:52:38 22 Q Do you recall that in Exhibit 1 of your reply report that
04:52:43 23 you had done a forecasting model that excluded the Wainwright
04:52:52 24 forecast?

04:52:53 25 A Yes. As we discussed, I have one model, but I was making

04:52:56 1 the point that even if one were to -- inappropriately, in my
04:52:59 2 opinion -- omit, exclude H.C. Wainwright, there's still a
04:53:04 3 positive NPV. You get a break-even point that occurs a little
04:53:09 4 bit later, but it doesn't change my conclusion, but, it's not
04:53:12 5 the model that I -- that I adopt.

04:53:19 6 Q So by excluding Wainwright, your claimed Net Present
04:53:24 7 Value decreased by approximately 1.52 billion; is that right?

04:53:29 8 A Yeah. I think that's the figure that came up this
04:53:32 9 morning.

04:53:32 10 Again, I'm not revising my model. My model is the
04:53:36 11 model from my original report. I'm just making the point that
04:53:40 12 there's benefit of having all five, and that's what I stick
04:53:44 13 to.

04:53:45 14 But even if one were to inappropriately omit one
04:53:48 15 analyst, it doesn't change the NPV conclusion. It changes the
04:53:53 16 break-even year and the NPV amount, but it's still positive.
04:53:58 17 Amarin would still be delivering a return to investors that
04:54:01 18 exceeds the industry average.

04:54:03 19 Q Okay. But, in any event, you would agree that by simply
04:54:06 20 removing just this one analyst, that the calculated Net
04:54:13 21 Present Value decreased by about 80 percent; is that correct?

04:54:16 22 A Yeah, that percentage sounds about right.

04:54:19 23 Q And when you include Wainwright in your Net Present Value
04:54:26 24 model, you determined a break-even point of, I think, 2024; is
04:54:31 25 that right?

04:54:32 1 A Yes.

04:54:32 2 Q And when you exclude Wainwright in your NPV model, you
04:54:38 3 end up in 2027; is that right?

04:54:40 4 A Yes, its 15th year on the market.

04:54:44 5 Q Now, each of the analysts' financial forecasts
04:54:49 6 substantially relied upon Vascepa results from the REDUCE-IT
04:54:54 7 trial, correct?

04:54:56 8 A Well, what was known at the time was the readout of the
04:55:00 9 data, I think in September of 2018. That was in the
04:55:04 10 information set for the analysts.

04:55:06 11 Q Right. But they were all anticipating that ultimately
04:55:10 12 Vascepa was going to get another label indication; is that
04:55:13 13 right?

04:55:14 14 A Well, I mean, several of them have what they call
04:55:18 15 scenarios, so they had, like, a base case, an upside, a
04:55:22 16 downside scenario.

04:55:23 17 But certainly, it would be -- you know, 90 percent
04:55:26 18 of new drug applications, and even higher of supplemental new
04:55:33 19 drug applications, get approved. So, they certainly could be
04:55:36 20 applying sort of an industry-wide, historical probability.

04:55:40 21 Q Okay. The Court can read these for herself, but the
04:55:43 22 bottom line is that you understand that in each of these
04:55:47 23 forecasts, all of the forecasts referred to the REDUCE-IT
04:55:52 24 results and built that into their forecasts; is that fair?

04:55:56 25 A Yes. That's clearly a part of the information set.

04:56:04 1 Q But you understand, don't you, that the REDUCE-IT trial
04:56:07 2 was directed toward patients with triglyceride levels below
04:56:13 3 500 milligrams per deciliter, right?

04:56:15 4 A I understand that the enrolled patients had those
04:56:18 5 characteristics.

04:56:19 6 My understanding of the label is that it's indicated
04:56:23 7 for reducing cardiovascular events for patients above 150. So
04:56:29 8 that would at least include the very high.

04:56:35 9 Q But as you testified earlier, right, your understanding
04:56:37 10 is that the claims do require a patient with 500 milligrams of
04:56:45 11 triglycerides or more, right?

04:56:46 12 A Yes. Without a legal background or clinical background,
04:56:51 13 that's my understanding, yes.

04:56:52 14 Q So you would agree, based upon your understanding, that
04:56:57 15 the REDUCE-IT trial is not related at all to the patient
04:57:04 16 population of 500 milligrams or more with respect to
04:57:07 17 triglycerides; is that right?

04:57:11 18 MR. M. KENNEDY: Objection. I think at this
04:57:12 19 point we're outside his proffer of what's related to what in
04:57:15 20 terms of clinical trials. I think he's stated the assumptions
04:57:19 21 behind his economic opinion.

04:57:21 22 THE COURT: Mr. Kennedy, you keep cutting in and
04:57:23 23 out. Why don't you remain seated and tell me your objection.

04:57:26 24 MR. M. KENNEDY: Oh. I apologize, Your Honor.

04:57:27 25 The objection is I think the question as posed

04:57:30 1 gets outside the realm of economics and into, sort of, a
04:57:34 2 scientific assessment of what trial is related to what, and so
04:57:38 3 I think that's outside of what Dr. Nicholson has been
04:57:41 4 proffered for.

04:57:42 5 THE COURT: Mr. Rounds?

04:57:44 6 MR. ROUNDS: Well, he certainly has proffered an
04:57:46 7 opinion as to nexus. And with respect to the assumptions that
04:57:49 8 he's made, I think I'm entitled to certainly ask questions
04:57:52 9 about whether or not REDUCE-IT falls within the scope of the
04:57:56 10 claims as he understands them.

04:58:00 11 THE COURT: Well, I'll allow it with that
04:58:02 12 limitation.

04:58:03 13 I understand the reason you're asking these
04:58:05 14 questions, but I do understand that Mr. Nicholson is not an
04:58:09 15 expert in the area of infringement and what the claims cover.
04:58:14 16 With that, I'll give his testimony the weight that I think is
04:58:18 17 appropriate.

04:58:20 18 MR. ROUNDS: Fair enough. I'll just ask one
04:58:21 19 follow-up question, Your Honor.

04:58:21 20 BY MR. ROUNDS:

04:58:23 21 Q You understand, don't you, that the patient population
04:58:26 22 for REDUCE-IT did not include patients with 500 milligrams or
04:58:31 23 more of triglycerides, right?

04:58:33 24 A That's -- you know, I didn't study that as part of my
04:58:39 25 assignment. That's my understanding of the patients who were

04:58:41 1 enrolled.

04:58:51 2 MR. ROUNDS: All right. Can you pull up

04:59:06 3 DDX 8.15.

04:59:06 4 BY MR. ROUNDS:

04:59:18 5 Q I believe you were shown this slide earlier in your
04:59:22 6 testimony. Do you recall this?

04:59:24 7 A I wasn't shown this, but this came up in Mr. Hofmann's
04:59:28 8 testimony.

04:59:28 9 Q Okay. And do you have any reason to dispute his numbers
04:59:31 10 with respect to marketing and sales expense of 575 million,
04:59:37 11 and cumulative net sales of 698 million through 2018?

04:59:42 12 A No, I believe those come from the financial statements.

04:59:46 13 Q And you --

04:59:47 14 A I'm sorry, I don't dispute them.

04:59:49 15 Q Okay. You would also not disagree that the marketing and
04:59:53 16 sales expense, as a percentage of net sales, was 82 percent;
04:59:58 17 is that right?

04:59:58 18 A Correct.

04:59:59 19 Q It's not your opinion, is it, that the \$575 million that
05:00:14 20 was spent through 2018 on marketing and sales is unrelated to
05:00:19 21 the success of the product; is it?

05:00:24 22 A Well, I mean, first, I just want to point out that the
05:00:29 23 data that I showed on marketing from IQVIA are gross sales,
05:00:35 24 you know, gross sales numbers and not net sales number.

05:00:39 25 But, no, I think -- you know, I understand from

05:00:42 1 studying this industry that when there's a new product on the
05:00:46 2 market, and physicians and health insurers and patients don't
05:00:50 3 know much about that market, it behooves a firm to make sure
05:00:53 4 that they provide information to key stakeholders and
05:00:58 5 decision-makers.

05:00:59 6 So -- but when I looked at the marketing message,
05:01:03 7 much of that content covers the patents that are being
05:01:07 8 asserted here. So, in that sense, if there is some causal
05:01:11 9 relation, it's -- it can arguably be stemming from the
05:01:15 10 patented features, marketing as the delivery mechanism to the
05:01:20 11 decision-makers.

05:01:21 12 Q Okay. Your testimony isn't that all of the marketing
05:01:24 13 that was done related to Vascepa related to the patented
05:01:31 14 features, is it?

05:01:33 15 A No. But certainly, you know, a substantial amount that I
05:01:37 16 observed was.

05:01:41 17 Q You understand that in approximately 2015 that Amarin
05:01:46 18 began promoting Vascepa to physicians based upon the ANCHOR
05:01:51 19 study; is that right?

05:01:52 20 A Well, my understanding is that the courts gave Amarin
05:01:56 21 permission, if they wanted to, to convey some information,
05:01:59 22 which I didn't study, to prescribers, not to consumers. But
05:02:04 23 the courts gave Amarin permission to convey some information
05:02:08 24 to prescribers.

05:02:09 25 Q So you haven't considered any information related to

05:02:14 1 promotional materials, or otherwise, that was used by Amarin
05:02:17 2 to promote the ANCHOR study to physicians?

05:02:21 3 A I didn't do that as part of my assignment, no.

05:02:28 4 Q Didn't you ask Amarin's attorneys for all of the
05:02:31 5 marketing information that was related to the promotion of
05:02:34 6 Vascepa?

05:02:37 7 A I had access to the material that was disclosed, and my
05:02:42 8 assignment was to look at the marketing material for evidence
05:02:48 9 that Amarin was marketing, and physicians were understanding,
05:02:53 10 the patent features that are in suit. I wasn't tasked with
05:03:00 11 doing a complete analysis of the marketing.

05:03:04 12 Q You understand, don't you, that there are many more
05:03:21 13 patients that fall within the 200 to 499 level of
05:03:26 14 triglycerides than the 500 or more triglycerides -- well,
05:03:33 15 strike that. Poor question.

05:03:34 16 You understand that there's a much bigger
05:03:38 17 marketplace for patients that have a triglyceride level of 200
05:03:43 18 to 499, as opposed to patients that have 500 or more; is that
05:03:48 19 right?

05:03:48 20 A Well, I do from, for example, the NDTI data, but that's
05:03:55 21 conditional on using Lovaza or Vascepa, what is the diagnosis
05:04:00 22 of the patient.

05:04:00 23 I didn't do any independent epidemiologic analysis
05:04:05 24 of the size of the -- potential size of those markets. In
05:04:08 25 terms of who's using those two drugs currently, yes, I would

05:04:13 1 agree.

05:04:13 2 MR. ROUNDS: Could you pull up Exhibit 576.

05:04:13 3 BY MR. ROUNDS:

05:04:21 4 Q You indicated in your report that you had reviewed this
05:04:24 5 document as part of your opinions; is that right?

05:04:27 6 A Yes. I believe so.

05:04:33 7 MR. ROUNDS: Could you go to page 36, please.

05:04:33 8 BY MR. ROUNDS:

05:04:41 9 Q Do you have page 36 in front of you?

05:04:44 10 A Yes, I do.

05:04:45 11 Q And do you see that on the left-hand side there is a
05:04:49 12 description of patients?

05:04:52 13 A Yes.

05:04:53 14 Q Okay. And do you see that there's a reference to MARINE,
05:04:59 15 500 or more milligrams of triglycerides per deciliter?

05:05:04 16 A Yes.

05:05:05 17 Q And do you see there's reference to 4 million?

05:05:07 18 A Yes, I do.

05:05:08 19 Q Okay. And do you understand that that's the potential
05:05:11 20 patient population for triglycerides of 500 or more milligrams
05:05:18 21 per deciliter?

05:05:19 22 A I'm not exactly sure what it's referring to, but I won't
05:05:22 23 dispute that.

05:05:23 24 Q Okay. Same question with respect to the ANCHOR
05:05:29 25 triglycerides. Do you see that?

05:05:30 1 A Yes, I do.

05:05:31 2 Q And do you see that's an indication of 200 to 499
05:05:36 3 milligrams of triglycerides per deciliter?

05:05:39 4 A Yes.

05:05:41 5 Q Okay. And that indicates a patient -- strike that.

05:05:45 6 That indicates a potential patient population of 35
05:05:50 7 million; is that right?

05:05:51 8 A Yes.

05:05:51 9 Q Do you have any reason to dispute that number?

05:05:54 10 A No, I don't have any reason to dispute it. I didn't
05:06:00 11 independently verify this, but I don't have any reason to
05:06:02 12 dispute it.

05:06:03 13 Q Okay. Given that background, would you agree with me
05:06:06 14 that the potential patients that could become customers of
05:06:10 15 Vascepa is much larger in the 200 to 499 space as opposed to
05:06:16 16 the 500 or more space?

05:06:18 17 A Yeah, I'll go back to my original conclusions. The
05:06:23 18 ability to get an FDA-approved indication gave physicians the
05:06:28 19 discretion to prescribe Vascepa for patients who have high,
05:06:34 20 and provided Amarin with funds that they could use to invest
05:06:39 21 into the REDUCE-IT trial.

05:06:42 22 So from a nonobviousness perspective, I believe all
05:06:47 23 of those sales should be included, as I did in my analysis.

05:06:52 24 Q Okay. My question was just a little bit more simple, and
05:06:55 25 that is, you don't have any reason to disagree with these

05:06:58 1 numbers, right?

05:06:59 2 A No, I don't.

05:07:01 3 Q Okay. And you agree with me that the market is much
05:07:04 4 larger for patients that have triglyceride levels of 200 to
05:07:11 5 499, as opposed to patients that have 500 or more; is that
05:07:16 6 fair?

05:07:17 7 A You know, I think I would want to know more about what
05:07:22 8 assumptions went into that, like, you know, what are the
05:07:25 9 assumptions about the probability that those patients would
05:07:28 10 want to have a prescription. I just haven't looked at that.

05:07:33 11 MR. ROUNDS: Your Honor, I would like to move
05:07:36 12 Exhibit 576 into evidence.

05:07:37 13 MR. M. KENNEDY: No objection, Your Honor.

05:07:38 14 THE COURT: 576 is admitted.

05:07:38 15 (Defendants' Exhibit 576 received in
05:07:38 evidence.)

05:07:38 16 BY MR. ROUNDS:

05:07:44 17 Q Let me direct your attention, if I could, to page 51 of
05:07:49 18 this exhibit. Do you see the reference to SWOT, Barriers and
05:07:56 19 Key Issues?

05:07:56 20 A Yes, I do.

05:07:58 21 Q Do you know that SWOT stands for Strengths, Weaknesses,
05:08:00 22 Opportunities and Threats?

05:08:01 23 A Yes.

05:08:07 24 MR. ROUNDS: Can you go to page 53.

05:08:07 25

05:08:07 1 BY MR. ROUNDS:

05:08:13 2 Q And do you see the reference to "Opportunities" at the
05:08:16 3 top?

05:08:17 4 A Yes, I do.

05:08:18 5 Q And there's an indication that "JELIS data supports
05:08:22 6 cardiovascular benefit of pure EPA."

05:08:24 7 Do you see that?

05:08:25 8 A Yes.

05:08:26 9 Q Do you have any knowledge or information that Amarin was
05:08:31 10 promoting Vascepa based upon the findings of a study called
05:08:36 11 JELIS?

05:08:38 12 A Well, my understanding -- and this wasn't part of my
05:08:41 13 assignment, I didn't conduct this analysis -- but my
05:08:44 14 understanding is JELIS is the data that's related to the
05:08:47 15 Court's decision to allow Amarin, perhaps with some
05:08:50 16 restrictions, to provide information to prescribers, potential
05:08:55 17 prescribers; so physician marketing, not consumer marketing.

05:09:00 18 Q So fair enough.

05:09:01 19 Based upon that knowledge, do you understand that at
05:09:05 20 least with respect to physicians, that Amarin, after the
05:09:10 21 decision in the FDA case, began to market the JELIS findings
05:09:16 22 to their physician population?

05:09:21 23 A Well, it wasn't part of my assignment. My understanding
05:09:24 24 is that that was a decision that the courts made that gave
05:09:27 25 Amarin permission -- again, perhaps with some restrictions --

1 to do such marketing.

2 Q Do you have any knowledge or information that they did do
3 that marketing to physicians and specifically referenced the
4 JELIS findings?

5 A I can't recall seeing that in my analysis.

6 MR. ROUNDS: Can you go to page 9 of this
7 document.

8 BY MR. ROUNDS:

9 Q Do you recall in your review in this case whether you
10 looked at this particular page of Exhibit 576?

11 A I can't recall seeing this.

12 Q Does this refresh your recollection at all that Amarin
13 was using the results of the JELIS study to promote Vascepa in
14 any way?

15 A Yeah. I mean, I will -- I don't see any evidence that
16 they were not using it. What I looked at in my analysis was
17 evidence that they were marketing the patented features to
18 physicians, and physicians were -- that was resonating with
19 physicians, they remembered it.

20 And physicians who were more likely to remember the
21 patent features were more likely to be prescribers, and to
22 intend to increase their use. So, that's what my analysis
23 focused on.

24 Q But, in any event, nobody provided you with materials
25 that showed that Amarin was promoting Vascepa to physician

05:11:18 1 customers with both the JELIS study and the results of the
05:11:24 2 ANCHOR study.

05:11:25 3 A Well, as I said, I had access to the documents that
05:11:28 4 were -- that were disclosed, but my assignment was not
05:11:32 5 broadened to include that.

05:11:39 6 Q Wouldn't you have wanted to know all ways in which Amarin
05:11:43 7 was marketing Vascepa?

05:11:47 8 A As I said, I -- you know, my assignment was to look for
05:11:53 9 whether there was evidence that Amarin was marketing the
05:11:58 10 ability of Vascepa to reduce TG without increasing LDL-C, two
05:12:04 11 of the patented features that are at issue here, to
05:12:08 12 physicians, and physicians -- and were physicians aware of
05:12:12 13 that, and were those -- was that awareness driving, in some
05:12:16 14 part, the commercial success.

05:12:29 15 MR. ROUNDS: Can you go back to PDX 5-5.

05:12:29 16 BY MR. ROUNDS:

05:12:43 17 Q Do you recall this exhibit during your examination?

05:12:47 18 A Yes, I do.

05:12:47 19 Q And do you see that in this document that the MARINE and
05:12:58 20 ANCHOR trials ended in the beginning of 2011?

05:13:03 21 A Yes. In 2011, yes.

05:13:06 22 Q And then REDUCE-IT began in about that same time frame;
05:13:10 23 is that right?

05:13:11 24 A Yes, that's correct.

05:13:13 25 Q Okay. So we can agree, can't we, that with respect to

05:13:20 1 R&D development costs, that most of those costs were incurred
05:13:26 2 from 2011 until 2018 for the REDUCE-IT trial?

05:13:33 3 A I don't have data on how the 22 million of R & D in 2011
05:13:40 4 was apportioned between those three trials, but I would agree
05:13:44 5 that from 2011 to 2018, that those funds were primarily for
05:13:51 6 REDUCE-IT.

05:13:51 7 Q And my math indicates that in that time frame about
05:13:56 8 \$352 million were spent by the company on the REDUCE-IT study,
05:14:00 9 based upon this exhibit. Does that sound right?

05:14:05 10 A Yes. Unless -- it's possible there is some other phase
05:14:09 11 for R&D that I'm not aware of. But, yes, I wouldn't disagree.

05:14:37 12 Q Let me direct your attention to PDX 5-25.

05:14:56 13 A Yes.

05:14:57 14 Q Is this a document that you pulled from Mr. Hofmann's
05:15:14 15 report and included in your slides for purposes of your
05:15:19 16 examination?

05:15:19 17 A Yes.

05:15:20 18 Q And this would include, as you understand it, from 2013
05:15:26 19 to 2018, revenue that was only related to patients that had
05:15:32 20 500 milligrams or more of triglycerides; is that correct?

05:15:36 21 A Yeah. These are estimates, and I think Mr. Hofmann
05:15:42 22 acknowledged that those percentages are too low. But, yes,
05:15:45 23 other than that, I would agree. The percentage is in the
05:15:52 24 middle.

05:15:53 25 Q Fair enough.

05:15:54 1 But, in any event, you would agree that if, in fact,
05:16:01 2 the relevant sales at issue here were 178 million through
05:16:08 3 2018, that this company could be in bankruptcy; is that right?

05:16:13 4 A Well, that's a hypothetical. It's not --

05:16:18 5 Q I get to ask those, by the way. Go ahead.

05:16:21 6 A But I think that's really not -- I don't know how germane
05:16:27 7 that is. In that world, there wouldn't be all these
05:16:30 8 substantial R&D costs that Amarin incurred for REDUCE-IT. So,
05:16:35 9 it doesn't seem to me to be a very informative type of
05:16:40 10 analysis.

05:16:41 11 Q Right. But, the REDUCE-IT trial didn't relate to
05:16:44 12 patients that had 500 milligrams or more of triglycerides,
05:16:49 13 isn't that true?

05:16:50 14 A No. My point is just -- it's important to be consistent.
05:16:53 15 If you're going --

05:16:53 16 Q Come back to my question, sir. Isn't that true?

05:16:57 17 A Could you repeat your question, please?

05:16:58 18 Q You understand that the REDUCE-IT trial didn't include
05:17:00 19 patients that had 500 milligrams or more of triglycerides,
05:17:04 20 right?

05:17:06 21 MR. M. KENNEDY: Objection. Asked and answered.
05:17:08 22 We've already gone over this.

05:17:09 23 THE COURT: I agree this question has been asked
05:17:12 24 several times. I don't think that's in dispute, Mr. Rounds.
05:17:16 25 Do you want to ask him another question?

05:17:20 1 MR. ROUNDS: Fair enough, Your Honor. I'll move
05:17:23 2 on.

05:18:14 3 Can you go back to Exhibit 576, please.

05:18:14 4 BY MR. ROUNDS:

05:18:24 5 Q Do you recall that we discussed this previously in your
05:18:26 6 testimony?

05:18:27 7 A Yes.

05:18:27 8 MR. ROUNDS: And can we go back to page 53.

05:18:27 9 BY MR. ROUNDS:

05:18:38 10 Q And do you see on the right-hand side there is the
05:18:41 11 reference to "threats"?

05:18:45 12 A Yes.

05:18:45 13 Q And about the fourth bullet down -- can you highlight
05:18:51 14 that for us? It says, "Lovaza still entrenched. Limited
05:19:00 15 appreciation of impact DHA has on LDL-C."

05:19:04 16 Do you see that?

05:19:05 17 A Yes.

05:19:06 18 Q Okay. That's a true statement, right, in 2017?

05:19:12 19 A Well, I guess I would say that's a true statement of some
05:19:18 20 scenario planning that Amarin was conducting.

05:19:22 21 Q Well, this indicates that it's a threat, right?

05:19:28 22 A Yeah, my -- well, I think my interpretation of SWOT
05:19:32 23 analyses is you try to understand the full range of
05:19:36 24 opportunities, threats, and weaknesses.

05:19:39 25 So, yeah, I would agree they're enumerating this as

05:19:42 1 something that merits some further review, at a minimum.

05:19:46 2 Q Do you have any reason to question that in 2017 Lovaza
05:19:53 3 was still entrenched in the marketplace?

05:19:58 4 MR. M. KENNEDY: Objection to the extent this is
05:19:59 5 seeking a scientific opinion. I'm not sure -- to the extent
05:20:04 6 it's seeking a scientific opinion, I object.

05:20:06 7 THE COURT: Mr. Rounds, I also think that what
05:20:10 8 you're asking this expert witness to do is to affirm or
05:20:13 9 endorse a document -- a statement in Amarin's document. He
05:20:19 10 can only testify as an expert.

05:20:21 11 So I don't know if it's fair to make him testify
05:20:24 12 as to that inference; that just because it's in Amarin's
05:20:28 13 statement he's going to say he thinks it's true.

05:20:31 14 Is that what you're trying to get at?

05:20:31 15 MR. ROUNDS: No, I mean, he --

05:20:32 16 THE COURT: I think it's an unfair question of
05:20:34 17 this expert witness.

05:20:36 18 MR. ROUNDS: Well, Your Honor --

05:20:36 19 THE COURT: So the objection is sustained unless
05:20:38 20 you have another way of approaching this.

05:21:53 21 MR. ROUNDS: Can you go to DDX 2.23.

05:22:05 22 No, that's not what I'm looking for.

05:22:09 23 Just give me one moment, Your Honor.

05:22:11 24 THE COURT: Yes.

05:22:31 25 MR. ROUNDS: All right. No further questions,

05:22:34 1 Your Honor.

05:22:34 2 MR. M. KENNEDY: Your Honor, Amarin has no
05:22:36 3 redirect.

05:22:36 4 THE COURT: All right. Thank you,
05:22:38 5 Mr. Nicholson. You may step down.

05:22:38 6 (The witness was excused.)

05:22:48 7 THE COURT: So I'm going to ask Miss Clerk to
05:22:50 8 tell counsel how much time each side has.

05:22:54 9 THE CLERK: Give me a second, Your Honor, to
05:22:56 10 calculate.

05:22:57 11 THE COURT: While she does that, to the extent
05:22:59 12 there's any confusion, because Miss Clerk had told me it
05:23:04 13 wasn't clear that Exhibit 655 has been admitted, I thought I
05:23:08 14 admitted that when Mr. Kennedy directed -- on direct
05:23:13 15 examination, and Mr. Rounds also asked about it.

05:23:16 16 So if there's any confusion, Exhibit 655 is
05:23:18 17 admitted.

05:23:19 18 MR. M. KENNEDY: All right. Thank you, Your
05:23:23 19 Honor.

05:23:23 20 THE COURT: And I'm asking about the time
05:23:30 21 remaining because I'm trying to plan for next week.

05:23:33 22 I'm assuming we will not proceed through the
05:23:35 23 entire week, given that -- I don't think you have that much
05:23:38 24 time left.

05:23:39 25 But, do you anticipate that you would conclude

on Wednesday?

MR. SIPES: Your Honor, Mr. Klein and I conferred, and that's our hope and expectation is to conclude by Wednesday.

MS. HUTTNER: Ms. Huttner agrees with that as well, Your Honor.

THE COURT: What's that?

MS. HUTTNER: That we will likely finish the testimony on Wednesday.

THE COURT: On Wednesday.

THE CLERK: Your Honor, the plaintiffs have used 839 minutes and the defendants have used 1,127 minutes.

THE COURT: Well, I'm going to allow some leeway. I probably will subtract the time used to argue the Rule 62 motion, if that was included. But, we'll see how it goes. So, I anticipate -- I'm not going to plan for trial on Thursday and Friday, and I anticipate that we will proceed through Wednesday.

Is there anything I need to address before we recess for the rest of the week and resume on Monday?

MR. SIPES: Not that we're aware of, Your Honor.

MR. KLEIN: No.

THE COURT: All right. Thank you.

(Court adjourned.)

-o0o-

I certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

/s/Kathryn M. French 2/1/2020
Kathryn M. French, CCR #392, RPR
Official Reporter

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